UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA

and

Ex Rel. Charles J. Wolf
942 East Ranch Circle
Draper, UT 84020

and

STATE OF CALIFORNIA,
STATE OF COLORADO,
STATE OF CONNECTICUT,
STATE OF DELAWARE,
THE DISTRICT OF COLUMBIA,
STATE OF FLORIDA,
STATE OF GEORGIA,
STATE OF HAWAII,
STATE OF ILLINOIS,
STATE OF INDIANA,
STATE OF IOWA,
STATE OF LOUISIANA,
STATE OF MARYLAND,
COMMONWEALTH OF MASSACHUSETTS,
STATE OF MICHIGAN,
STATE OF MINNESOTA,
STATE OF MONTANA,
STATE OF NEVADA,
STATE OF NEW JERSEY,
STATE OF NEW MEXICO,
STATE OF NEW YORK,
STATE OF NORTH CAROLINA,
STATE OF OKLAHOMA,
STATE OF RHODE ISLAND,
STATE OF TENNESSEE,
STATE OF TEXAS,
COMMONWEALTH OF VIRGINIA,
STATE OF WASHINGTON, AND
STATE OF WISCONSIN

Plaintiffs,

Case No. _____
FILED UNDER SEAL
Pursuant to 31 U.S.C. §3730
(False Claims Act)

v.

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT 84095

Defendant.

COMPLAINT AND DEMAND FOR JURY TRIAL

OVERVIEW

1. This is a civil action by Relator Charles J. Wolf , by and through undersigned counsel, who files this False Claims Act ("FCA") Complaint on behalf of himself, the United States of America, and the states of California, Colorado, Connecticut, Delaware, District Of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and Wisconsin against Defendant Merit Medical Systems, Inc. ("Merit") for damages and civil penalties arising out of Defendant's violations of the Federal False Claims Act, 31 U.S.C. §§3729-3733 *et seq.*, the Federal Anti-Kickback Statute related to causing improper payments from Medicaid, Medicare, VA hospitals, and other federally and state-funded government healthcare programs.

2. This is an action for money damages, including treble damages and civil penalties, on behalf of the United States of America under the Federal False Claims Act, 31

U.S.C. §§3729-33 (FCA), Anti-Kickback Statute, 42 U.S.C. §1320a-7b, and the Food, Drug and Cosmetic Act, 21 U.S.C. §§301-397 ("FDCA") and the various, similar state statutes, arising from false and/or fraudulent statements, records, and claims caused to be made by the Defendant Merit and/or its agents and employees, for its intentional, false and misleading off-label marketing campaigns, and for its continuing scheme to pay kickbacks in the form of improper compensation to providers to illegally induce them to use Merit devices for both on and off-label use, and for sustaining a fraudulent course of conduct to obtain improper and unwarranted government reimbursement, all in violation of the FCA.

3. In summary, this *qui tam* case is brought against Merit for causing the submission of false claims for services, for misrepresentations to the Food and Drug Administration ("FDA") and others, for Merit's false and misleading off-label marketing of its QuadraSphere Microsphere, Embosphere, Endotek devices, and its CO2 kits and for its systematic violation of the Federal Anti-Kickback Statute, particularly relating to its Local Advertising Program ("LAP") and consulting fees.

4. Through its LAP program, Merit systematically pays kickbacks to primarily induce the use and purchase of Embosphere and QuadraSphere paid for by Federal and state health care programs. Merit has violated the Federal Anti-Kickback Statute, 42 U.S.C. §1320a-7b ("AKS") and similar state statutes, by, *inter alia*, offering and providing illegal remuneration to physicians and hospitals, in the form of marketing and advertising dollars (disguised as "educational grants"), speaking fees, consulting fees, writing fees, dinners, trips and other cash, as a *quid pro quo* and inducement to use Embosphere and QuadraSphere and other Merit devices to the exclusion of other devices and for both on and off-label indications. Merit's violations of the AKS give rise to liability under the FCA.

5. As relates to Merit's LAP program, it funds the marketing, promotion and advertising for providers who do significant business with Merit already and whose business Merit seeks to keep, or, whose business Merit wants to obtain or grow.

6. Through the LAP, there is a clear and recognized intent by Merit to affect and induce: (1) what device the receiving providers use (Merit devices over those of its competition); (2) the amount or volume of use by the provider of Merit devices; and (3) how or for what the provider uses the Merit device (often for off-label use). Internal communications confirm that these funds are not educational by any means, but are instead intentionally meant to effect and induce providers to use Merit devices and to steer providers to use Merit devices exclusively. Funds are approved and tracked with an eye toward ROI (return on investment) for Merit. Though funded by Merit, most of the LAP advertisements do not mention Merit or note any relationship with or contribution by Merit. This program violates the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) and various similar state anti-kickback statutes.

7. Merit has continued its predecessor's program of paying for advertising for high-volume users of its medical devices and continues to pay consulting fees to high-use providers for little-to-no work. Merit's only effort at reforming these practices has been perfunctory. The purpose of giving away some devices (Maestro), wining and dining physicians, paying for physician trips to extravagant locations, paying physicians exorbitant speaker fees, paying for physician advertising and referrals, and paying consulting fees and honoraria for little-to-no work, was to gain market share at inflated prices, as well as to induce hospitals and physicians to purchase additional equipment, supplies, and/or products from Merit. As Merit knew would happen, the physicians or hospitals in turn submitted claims to

Medicare and Medicaid for procedures performed with Merit medical equipment, bringing Merit's financial inducements within AKS.

8. Management often openly joked about compliance; coming up with a numeric system to discuss internally how risky, from a compliance standpoint, certain proposals would be. They assessed risk and rated proposed actions on a "chili pepper" scale of 1-3, in terms of how much "heartburn" a particular action would give the company in terms of compliance and ethics concerns.

9. Merit knew the Federal government and the various states would ultimately pay for a large portion of its medical products sold to its customers and "educational grantees." It also knew that its customers would seek payment from government health care programs. Merit also knew that its customers were required to certify compliance with anti-kickback laws on cost reports as a condition of payment, and that their kickbacks would cause the certifications and cost reports to be false. Therefore, Merit is liable under the FCA for knowingly causing customers to submit false certifications of compliance with the AKS and to submit false claims to get government funds paid or approved by the United States.

10. Further, despite knowing that millions of dollars in payments from the Federal and state governments have been received in violation of the Stark statute's prohibition on receipt of payment for services rendered despite an improper financial arrangement, Defendant has failed to refund these payments as required by the Stark statute. Under the False Claims Act, 31 U.S.C. § 3 729(a)(l)(G) (2009), this constitutes a knowing and improper avoidance of an obligation to transmit money to the government.

11. In addition to the kickbacks paid specifically to high-volume Embosphere and QuadraSphere users, Merit has made systematic kickback payments to physicians to induce the

use of Merit products and devices. This includes consulting fees paid even though no work is performed and Merit-sponsored lunches and dinners wherein Merit pays the speaker fee, pays for the meals for the attendees and where the speaker discusses off-label uses of Merit devices including QuadraSphere and Embosphere. This also includes lavish, all expenses paid, trips to desirable destinations like Paris, Ireland and Hawaii.

12. Merit paid kickbacks to providers in an amount estimated at or more than $2 million per year since 2010, and tainting far more than that in claims submitted by providers to Medicare, Medicaid, the VA, and other Federal and state health care programs.

13. Merit's extensive kickback activities also violate the Foreign Corrupt Practices Act of 1977, as amended, 15 U.S.C. §§ 78dd-1, *et seq.*, ("FCPA") as they involve inducing the decision-making of foreign officials to use its products.

14. Merit understands that it is subject to these laws. Its 2015 10-K states in part, "we are also subject to the FCPA, the U.K. Bribery Act, and similar anti-bribery laws in non-U.S. jurisdictions. These laws generally prohibit companies and their intermediaries from illegally offering things of value to any individual for the purpose of obtaining or retaining business. As we continue to expand our business activities internationally, compliance with the FCPA and other anti-bribery laws presents greater challenges to our operations."

15. Further, Merit has and continues to engage in a systematic and intentional scheme of false and off-label marketing and promotion of its QuadraSphere and Embosphere devices.

16. QuadraSphere Microspheres indicated for the "embolization of hypervascularized tumors and peripheral vascular arteriovenous malformations (AVMs)" per the initial 510(k). There is no particularized indicated condition or disease for QuadraSphere.

In 2010, the FDA approved a phase III clinical trial meant to evaluate the safety and efficacy of QuadraSphere in patients with localized, unresectable hepatocellular carcinoma. This trial is on-going.

17. Generally, the false and misleading statements and claims made by Merit regarding QuadraSphere include, but are not limited to, the following:

i) False and misleading statements and omissions by Merit in training materials, device training to doctors and promotional materials stating that the QuadraSphere is indicated for more than hypervascularized tumors and peripheral vascular arteriovenous malformations, such as for primary and metastatic liver cancer, when it is not so indicated in this country;

ii) False and misleading statements and omissions by Merit that QuadraSphere is safe and effective to treat primary and metastatic liver cancer, when it has not been so proven and is, in fact, still in clinical trials mandated by the FDA to determine safety and efficacy; and

iii) False and misleading statements and omissions by Merit that QuadraSphere is indicated to be used with doxorubicin, irinotecan and oxaliplatin to treat liver cancer when it is not so indicated.

18. According to its initial 510(k), Embosphere Microspheres are "spherical microbeads for arterial embolization made of acrylic polymer impregnated with gelatin. They are delivered with the help of a microcatheter in an amount appropriate to the area to be embolized."

19. Embosphere was originally indicated for the embolization of hypervascular tumors and arteriovenous malformations. A later 510(k) indicated specifically for the embolization of uterine fibroids.

20. Embosphere is not indicated for gastric artery embolization for bariatric treatment purposes.

21. Since 2013, Embosphere has been the subject of a clinical trial to study its safety and effectiveness for prostatic artery embolization (PAE). This clinical trial is ongoing and Embosphere is not currently indicated for PAE.

22. Generally, the false and misleading statements and claims made by Merit regarding Embosphere include, but are not limited to, the following:

i) False and misleading statements and omissions by Merit in training materials, device training to doctors and promotional materials stating that the Embosphere is indicated for more than the embolization of hypervascular tumors and arteriovenous malformations and uterine fibroids, such as to embollize the arteries feeding the stomach and prostate, when it is not so indicated in this country; and

ii) False and misleading statements and omissions by Merit that Embosphere is safe and effective for the embolization of the arteries feeding the stomach and prostate, when it has not been so proven and is, in fact, still in clinical trials mandated by the FDA to determine safety and efficacy.

23. In the course of its off-label marketing schemes, Merit has made false and misleading statements to physicians and others to the effect that QuadraSphere and Embosphere were FDA-approved or indicated for the off-label uses being promoted, and therefore are eligible for Medicare, Medicaid and other Federal and state health care program reimbursement.

24. In reliance on Merit's false and misleading statements, physicians used and continue to use QuadraSphere and Embosphere on their patients in off-label and non-FDA-approved uses. Thus, Merit caused and continues to cause physicians to present false claims for payments to Medicare, Medicaid and other Federal and state health care programs. Merit's false statements caused certain QuadraSphere and Embosphere devices to be unapproved Class II medical devices used in interstate commerce. Additionally, Merit's false and misleading statements led to the submission and payment of false claims by Medicare, Medicaid, the VA

and other Federal and state health care programs, which violates Section 3729(a)(l)(a),(b),(c) of the FCA. Merit intended its off-label marketing, training and promotion to cause the submission of false claims and to result in improper payments by Federal and state health care programs.

25. Merit's false and misleading statements and omissions in regard to the QuadraSphere and Embospohere devices caused others to submit false claims for reimbursement to Medicare, Medicaid and other Federal and state health benefit programs, claims that would not have been paid if those health benefit programs had been fully informed about the lack of approval for indicated uses promoted by the Defendant and lack of safety and efficacy through on-going clinical trials.

26. Merit knew or should have known that its conduct, representations and omissions were contrary to Federal and state laws, were without FDA approval, were off-label and were creating a dangerous medical situation for unsuspecting patients.

27. As the direct, proximate and foreseeable result of Merit's false and fraudulent conduct as set forth herein, Merit: (a) caused physicians and hospitals to submit false claims to Medicare, Medicaid and other federal and state health care programs seeking reimbursement for uses of QuadraSphere and Embosphere that Merit knew were not approved by the FDA and were off-label and therefore ineligible for Federal and state health care program reimbursement; (b) used false or fraudulent statements to get Federal and state health care programs to reimburse millions of dollars in false and fraudulent claims submitted by these physicians; and (c) used improper and unlawful kickbacks to induce physicians' use of Merit devices both on and off-label.

28. Merit's illegal scheme to promote the use of QuadraSphere and Embosphere for indications that were not FDA approved and have not been proven safe and effective greatly increased QuadraSphere and Embosphere's sales to the great financial benefit of Merit, but caused Federal and state health care programs to pay millions of dollars for the use of medical devices that were not approved, were not reasonable and medically necessary and were medically unsafe for non-approved uses.

29. In addition to the false and off-label marketing and promotion of QuadraSphere and Embosphere, Merit has also continued the false and off-label practices of its predecessors as relates to its Endotek devices.

30. In general, Merit inherited and chose not to change, but to continue, the off-label and false promotion and marketing from companies that is it has acquired. This extends to its stent device too. Merit's Endotek's gastroenterology stents are indicated and supposed to be used to treat esophageal cancer (malignancy), but they are promoted and marketed by Merit for use in bariatric surgery for bariatric leaks and marketed off-label for treating non-malignant narrowing of the esophagus.

31. Lastly, Merit also engages in the false and off-label promotion and marketing of its CO2 kits. CO2 is used as a replacement for contrast for patients who cannot tolerate normal contrast. Merit had a CO2 kit packaged together, but for which it decided formal FDA approval would take too long, be difficult and too onerous a process to undergo. Merit decided then to not attempt to get the indication, and to discontinue it as a packaged kit. However, Merit did not disclose to the FDA or otherwise note anywhere that it continues to sell the exact components of the kit as 3 separate items that get purchased together. In other words, after inquiring with the FDA and deciding it would be too complicated or difficult to get the

indication, Merit simply started selling the exact same items, just de-packaged so as to avoid FDA detection.

32. As a direct result of Merit's improper practices as detailed herein, the Federal Treasury and those of the states named herein have been damaged in a substantial amount that is yet to be determined, but currently estimated at tens of millions of dollars or more.

PARTIES AND ENTITIES

33. The United States, through the Department of Health and Human Services ("HHS") and, HHS's Centers for Medicare and Medicaid Services ("CMS"), is the real party-plaintiff in interest in this action. HHS's headquarters are located at 200 Independence Avenue S.W., Washington, D.C., 20201. CMS's main office is located at 7500 Security Boulevard, Baltimore, MD 21244.

34. Plaintiff-Relator Charles Wolf is a resident of the State of Utah. Relator was the Chief Compliance Officer for Defendant Merit from August, 2011 through October 2015, working at its principal office in South Jordan, Utah. In this capacity, Relator reviewed marketing, sales, trainings, and communications, attended sales training sessions, reviewed the global anti-corruption program (FCPA), Sunshine Act compliance, import-export law, conflict minerals (Dodd Frank Act), and some product liability matters. Generally, he reviewed Merit programs for compliance with various federal and state laws and made recommendations, but was not the end decision-maker. Relator is a medical doctor but has worked exclusively in the compliance field since 1999. He is a Certified Compliance and Ethics Professional by the Society of Corporate Compliance and Ethics and was certified in Healthcare Compliance by the Health Care Compliance Association. He has taught professional courses on such topics as medical billing, coding and regulations.

35. Relator reported all of the fraud detailed herein to the management at Merit during his tenure. However, his concerns were nearly always given only token respect. For years, there was no effort to investigate, let alone overhaul, the programs that were most troubling to the Relator, including kickbacks and off-label promotion. Upon information and belief, another officer (Chief Regulatory Affairs Officer) had been run out of the company shortly after his arrival for voicing similar concerns to those eventually voiced by Relator and for being too rigid on compliance for Merit. In the spring and summer before Relator left Merit in October 2015, an investigation was finally initiated into the off-label promotion of QuadraSphere after an anonymous tip of this fraud reached the Board of Directors. However, even after a new policy was written, the sales and marketing division was adamantly opposed to its implementation, often times commenting to Relator that if they complied, they would be out of work as sales would simply dry up. Given the culture and refusal to implement the change needed, Relator submitted his resignation.

36. Defendant Merit Medical Systems, Inc. is a Utah corporation incorporated in 1987 with a principal place of business of 1600 West Merit Parkway, South Jordan, UT 84095. Merit is a publicly-held medical device company traded on the NASDAQ as "MMSI." Merit's operations focus primarily in the following areas: diagnostic and interventional cardiology, interventional radiology, interventional gastroenterology, interventional pulmonology, vascular surgery, interventional nephrology, and thoracic surgery. As of December 31, 2015, Merit reported 3,754 employees. Merit sells both domestically and internationally, with its domestic sales generally ranging between 61% and 65% of total sales. Net sales have grown significantly year over year, starting at $296,755,000 in 2010 and hitting $542.1 million in

2015. Gross profit followed suit, starting at $128,498,000 in 2010 and reaching $235,781,000 in 2015 according to the company's 10K filings.

JURISDICTION AND VENUE

37. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and 31 U.S.C. §3732. 31 U.S.C. §3732 specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730.

38. This Court has personal jurisdiction over the Defendant pursuant to 31 U.S.C. § 3732(a), because it authorizes nationwide service of process and because the Defendant has at least minimum contacts with the United States. Moreover, the Defendant can be found in New Jersey, transacts business in New Jersey, markets in New Jersey, pays kickbacks to New Jersey providers and sells its devices to New Jersey hospitals and physicians. According to its public filings, Defendant also leases office space in New Jersey, from which it conducts business.

FCA SUBJECT MATTER JURISDICTION

39. Upon information and belief, none of the subject matter or other jurisdictional bars set forth in the FCA is applicable to this action.

40. Upon information and belief, prior to any "public disclosure" (as defined by the FCA), RELATOR voluntarily disclosed to the United States Attorney's Office for the District of Maryland on January 19, 2016 and the United States Attorney's Office for the District of New Jersey on March 2016, the information on which the allegations or transactions in this complaint are based.

41. Through his employment at Defendant Merit, RELATOR is an "original source" of the information on which these allegations are based, within the meaning of the FCA.

42. Prior to filing this action, on and before March 21, 2016, RELATOR voluntarily disclosed to the United States Attorney's Office for the District of New Jersey the information on which the allegations or transactions in his complaint are based.

FACTS COMMON TO ALL COUNTS

FDA Regulation of Medical Devices

43. The FDA is an agency of the United States Government responsible for protecting the health and safety of the public by assuring, among other things, that medical devices intended for use in the treatment of humans are safe and effective for their intended uses and that the labeling of such devices bear true and accurate information.

44. Pursuant to its statutory mandate, the FDA regulates the manufacture, labeling, and shipment in interstate commerce of medical devices.

45. Under the Federal Food, Drug and Cosmetic Act (Title 21, United States Code, §§301-397, the "FDCA"), and pursuant to Title 21, United States Code § 321(h), the term "device" includes "an. . . implant . . . or other similar or related article. . . which is … intended for use in. . . the treatment or prevention of disease of man... or intended to affect the structure or any function of the body of man. . . which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

46. The FDA is charged with protecting American consumers by enforcing the FDCA of 1938, the FDA Modernization Act of 1997 and related public health laws. Under the FDCA, the FDA has the responsibility of ensuring that medical devices are safe and effective before they can be marketed within the United States. The FDA's authority to regulate medical devices arises in part from the FDCA, as amended by the Medical Devices Act of 1976 ("the

1976 Amendments"). General statutory standards for determining the safety and effectiveness of devices are set forth in the FDCA, 21 U.S.C. §§360c(a)(2) and (a)(3). These standards are implemented by regulations set forth at 21 C.F.R. §860.7.

47. Under Federal law, medical devices are classified into Class I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type.

48. The U.S. FDA classifies medical devices based on the risks associated with a particular device. Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. Class II devices are higher risk devices and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness. Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control. Class III devices must typically be approved by FDA before they are marketed.

49. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval.

50. To market a Class II device, manufacturers are typically required to submit a 510(k) Premarket Notification to the FDA, unless the device is determined to be exempt from the 510(k) requirements.

51. In submitting a 510(k), the manufacturer must demonstrate that the device is at least as safe and effective (*i.e.* that the device is "substantially equivalent") to a legally marketed device (21 C.F.R. 807.92(a)(3) ("predicate device")). A legally marketed device, as described in 21 C.F.R. 807.92(a)(3), is a device that was legally marketed prior to May 28,

1976; a device which has been reclassified from Class III to Class II or I by the FDA; or a device which has already been found substantially equivalent through the 510(k) process.

52. A device is substantially equivalent if, in comparison to a legally marketed device, it: (1) has the same intended use; and (2) has the same technological characteristics as the legally marketed device OR has different technological characteristics and the manufacturer submits information to the FDA which does not raise new questions of safety or effectiveness and/or demonstrates that the device is as safe and effective as the legally marketed device.

53. For Class II medical devices requiring Premarket Notification, the manufacturer may not proceed to market the device in the United States until the manufacturer receives an order from the FDA declaring a device to be "substantially equivalent" to a predicate device.

54. Premarket Notifications are governed largely by 21 CFR Part 807 Subpart E. A 510(k) must demonstrate that the device is substantially equivalent to one legally, commercially distributed in the United States: (1) before May 28, 1976; or (2) to a device that has been determined by FDA to be substantially equivalent.

55. Under the CFR, a 510(k) is required when:

a.) Introducing a device into commercial distribution (marketing) for the first time after May 28, 1976;

b.) A **different intended use** is proposed for a device which is already in commercial distribution. 21 CFR 807 specifically requires a 510k submission for a major change or modification in intended use. **Intended use is indicated by claims made for a device in labeling or advertising. Most, if not all changes in intended use will require a 510(k)**; or

c.) There is a change or modification of a legally marketed device and that change could significantly affect its safety or effectiveness.

21 CFR 807.81. (Emphasis supplied). A few Class II devices are expressly exempt from Premarket Notification, none of which apply here.

56. If the FDA makes a finding of "substantial equivalence" based on the manufacturer's Premarket Notification, the device is then "cleared" for marketing and can be marketed only for the intended use stated on the label as cleared by the FDA.

57. If the manufacturer intends to market the device for a new or different intended use from that cleared for the predicate device, a new 510(k) Notification is required to include supporting information to show that the manufacturer has considered what consequences and effects the new use might have on the device's safety and effectiveness.

58. According to the FDA, "Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices."

59. The manufacturer of a medical device is not permitted to promote its device for any use other than the intended use on the label as cleared or approved by the FDA.

60. A medical device is "misbranded" if the manufacturer of the device has failed to provide the FDA with Premarket Notification of a new or non-FDA-sanctioned intended use ninety days prior to introducing the device into interstate commerce for such use.

61. The FDCA also contains provisions on misbranding and false or misleading labeling. According to Section 502, a device is misbranded if: its labeling is false or misleading in any way; its label does not bear adequate directions for use, including warnings against use

in certain pathological conditions; it is dangerous to health when used in the dosage or manner or with the frequency or duration prescribed, recommended or suggested in the labeling.

62. A device may be deemed "misbranded" if its label, including *all* written, printed, or graphic matter upon any article or any of its containers or wrappers or any other thing accompanying such article, at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce, fails to reveal material facts, the consequences that may result from use, or the existence of a difference of opinion about its appropriate use. *See, e.g.* 21 U.S.C. §§ 331(a) and (b), 352(a), (I) and (n); 21 C.F.R. § 201.57. The term "accompanying" a product, as used in Section 502, has been interpreted by the courts to include posters, tags, pamphlets, circulars, booklets, brochures, instruction books, etc. and "most if not all advertising" about the product.

False Claims Act

63. The False Claims Act provides, in pertinent part, that any person who:

> **(A)** knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> **(B)** knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> **(C)** conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
> ...
> **(G)** knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410[1]), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729.

64. For purposes of the False Claims Act, the terms "knowing" and "knowingly" mean that a person, with respect to information; (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud. 31 U.S.C. § 3729(b).

65. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the False Claims Act civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

The Medicare Program

66. Medicare is the Federal health insurance program that was created in 1965 when Title XVII of the Social Security Act was adopted. 42 U.S.C. §§ 1395, *et seq*. Medicare covers people of age 65 and older regardless of their income or medical history. Coverage extends to about 46 million Americans.

67. Medicare is organized into four parts. Part A pays for inpatient hospital stays, skilled nursing facility stays, home health visits (also under Part B), and hospice care. Part B covers physician visits, outpatient services, preventive services, and home health visits. Part C, the Medicare Advantage program, allows beneficiaries to enroll in a private health organization, such as a health maintenance organization (HMO), and receive all Medicare-covered benefits. Part D is the voluntary, subsidized outpatient prescription drug benefit.

68. The Centers for Medicare and Medicaid Services (CMS) administers Medicare. However, most of the daily administration and operation of the Medicare program is managed

through contracts with private insurance companies that operate as Fiscal Intermediaries. Fiscal Intermediaries accept and pay reimbursement claims under Medicare Part A and some claims under Part B. Acceptance and payment of claims under Medicare Part B are completed through "Medicare Carriers."

69. CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions. 42 C.F.R. §405.201.

70. Medicare may reimburse for Class II devices if they are approved by the FDA pursuant to the Premarket Notification process.

71. Under Medicare regulations, Medicare will not reimburse providers or institutions or medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not "reasonable" and "necessary" under section I 862(a)(l)(A) of the Act or because it is excluded from coverage for other reasons. Medical devices that are not approved for marketing by the FDA are considered investigational by Medicare and are not considered reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures and services performed using devices that have not been approved for marketing by the FDA. Services that are excluded from coverage include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from related noncovered services.

The Anti-Kickback Statute

72. The Anti-kickback Statute ("AKS") prohibits any person or entity (including physicians or hospitals) from "knowingly and willfully" soliciting, receiving, offering or paying "any remuneration, indirectly, overtly or covertly, in cash or in kind" in return for "referring an individual to a person for the furnishing of any item to or service for which payment may be made in whole or in part under a federal health care program." 42 U.S.C. §1320a-7b(b)(l) & (2). This includes intent to induce referrals or business orders, including the utilization of medical devices paid as a result of the volume or value of any referrals or business generated. *See* 42 C.F.R. §1001.952(f).

73. The definition of "federal health care program" for purposes of the AKS includes Medicare, Medicaid and Tricare. This provision makes it unlawful for a physician to make a referral that will lead to a claim being submitted to Medicare for services or products supplied by an entity (such as a medical device company) with which the physician has a financial relationship, unless the relationship is not intended to induce referrals and is exempt under a statutory or regulatory safe harbor.

74. The AKS was passed because of Congressional concerns that payoffs, to those who can influence health care decisions, will result in goods and services being provided that are medically unnecessary, or even harmful, to a vulnerable patient population. To protect the integrity of Federal health care programs from these difficult-to-detect harms, Congress enacted a prohibition against the offer or payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality care.

75. The Balanced Budget Act of 1997 amended the Medicare Anti-Kickback Statue to include administrative civil penalties of $50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three times the amount of remuneration

offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. *See* 42 U.S.C. §1320a-7a(a).

76. Such remunerations are kickbacks when paid to induce or reward physicians' utilization of medical devices. Kickbacks increase Government-funded health benefit program expenses by inducing medically unnecessary overutilization of prescription drugs, medical devices and excessive reimbursements. Kickbacks also reduce a patient's healthcare choices, as a physician may use a medical device based on the physician's own financial interests rather than according to the patient's medical needs or safety.

77. The Medicare Anti-Kickback Statute contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. §1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protect Merit's conduct in this case.

78. The Patient Protection and Affordable Care Act ("PPACA"), Public Law No. 111-148, Sec. 6402(g), amended the Medicare Anti-Kickback Statute or "Social Security Act," 42 U.S.C. §1320a-7b(b), to specifically allow violations of its "anti-kickback" provisions to be enforced under the False Claims Act. PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of the Social Security Act's anti-kickback provisions, like violations of the False Claims Act, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation."

79. At all times relevant herein, compliance with the Anti-Kickback Statute has been a condition to participation for a health care provider under Medicare, Medicaid and other federally and state-funded healthcare programs. Moreover, compliance with the AKS is a condition of payment for claims made to such programs for reimbursement for services

80. The Anti-Kickback Statute not only prohibits outright bribes, but also prohibits any payment or other remuneration by a manufacturer to a physician or other person or entity which has as one of its purposes the inducement of the physician to perform procedures using the manufacturer's products or to induce the physician to influence or recommend use of the manufacturer's product.

81. In addition, certain providers, such as hospitals, participating in Federal healthcare programs must annually certify compliance with the AKS. For hospitals, this certification is included in the CMS Form 2552 cost report that such providers are required to submit. Medicare and its designees rely on this certification and the representations made therein in making payments to providers. The "advisory" language preceding the certification section reads as follows:

> MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CNIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, **IF SERVICES IDENTIIFIED BY THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECILY OR INDIRECILY OF A KICKBACK OR WERE OTHERWISE ADMINISTRATIVE ACTION, FINES, RESULT**.

(Capitals in original; bold emphasis added). The specific certification language then reads:

> CERTIFICATION BY OFFICER OR ADMINISTRATOR OR PROVIDER(S)
> I HEREBY CERTIFY that I have read the above statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by [Provider Name(s) and Number(s)] for the cost reporting period beginning [date] and ending [date] and that to the best of my knowledge and belief it is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted **I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.**

(Capitals in original; bold emphases added)

82. Payment to Providers under Federal healthcare programs - not just participation in those programs - is conditioned upon this express certification that the Provider has complied with the AKS. Providers' suppliers are also bound by the rules and regulations underlying the AKS. *See* § 1001.952(h)(2). Thus, the CMS Form 2552 cost reports submitted to Medicare and Medicaid programs by any provider receiving kickbacks from the Defendant were false for purposes of the FCA because they contained a false certification of AKS compliance.

83. The "safe harbor" provisions of the AKS apply to certain narrow forms of payment *(see* 42 U.S.C § 1320a-7b(b)(3)(A) and (b)(3)(E); 42 C.F.R. § 1001.952(h)), but Relator does not bear the burden of alleging or proving inapplicability of the safe harbor as an element of the claims pleaded here. Regardless, as set forth *infra*, the safe harbor provisions do not apply to any of the payments or conduct alleged herein.

84. None of Merit's kickbacks met the conditions of the regulatory safe harbor. Specifically, all of the kickbacks violated one or more of the safe harbor's requirements that a payment: (1) is an arms-length reduction in the amount a buyer was charged; (2) with terms fixed at the time of the initial purchase; (3) fully and accurately reported on the invoice or statement submitted to the buyer at the time of sale; and (4) followed by documentation of the discount's calculation and the specific goods purchased to which it applied.

The Stark Law

85. The Medicare/Medicaid Self-Referral Statute, 42 U.S.C. § 1395nn *et seq.,* known as the "Stark law" after Congressman Pete Stark, prohibits a physician from making a referral that will lead to a claim being submitted for "designated health services," the definition of

which encompasses services rendered using equipment manufactured by Merit, where the referring physician has a nonexempt "financial relationship" with the manufacturer. 42 U.S.C. § 1395nn(a)(l), (h)(6). The Stark law provides that the manufacturer shall not cause to be presented a Medicare or Medicaid claim for such services.

86. The Stark law also prohibits payment of claims rendered in violation of its provisions. 42 U.S.C. §1395m(a)(l),(g)(1).

Merit Medical Overview

87. Merit focuses its operations on four primary areas: diagnostic and interventional cardiology, interventional radiology, interventional gastroenterology and interventional pulmonology.

88. This Complaint largely focuses on Merit's interventional radiology operation. Within that operation, Merit markets a number of embolic products, including the following which are particularly relevant here: (1) Embosphere Microsopheres; (2) HepaSphere Microspheres; and (3) QuadraSphere Microspheres.

89. QuadraSphere and Embosphere were developed and originally distributed by BioSphere Medical, a company acquired by Merit in September 2010.

90. Merit employs approximately 3,754 employees company-wide. It employs direct sales representatives to market and sell its devices. In 2014, Merit reorganized its U.S. direct sales force into two divisions: (1) the cardiovascular division ("CVD"); and (2) the interventional procedure division ("IPD"). The CVD has 54 sales representatives, and the IPD has 37 sales representatives. This salesforce is nationwide, including in New Jersey.

Specific Allegations

Unlawful Kickbacks

The Local Advertising Program (LAP)

91. Merit has and continues to fund a program internally called the "LAP" (Local Advertising Program). This program funds the marketing and advertising for providers and hospitals which do significant business with Merit or whose business Merit wants to obtain or grow. These funds are categorized internally as "educational grants," but there is a clear and recognized intent by Merit to affect: (1) what device the receiving providers use (Merit devices over those of the competition); (2) the amount or volume of use by the provider of Merit devices; and (3) how or for what the provider uses the Merit device (often for off-label use).

92. Upon information and belief, at least $750,000 was earmarked and used each year for the LAP program. At other times, other funds (from, for example, the general fund) were used to partially pay or cover these payments.

93. The LAP program primarily seeks to induce the sale and use of Embosphere with a secondary target of inducing the sale and use of QuadraSphere. It also induces the use of other Merit products such as catheters, guidewires and other devices used in embolization procedures.

94. Merit keeps track of the ROI of its LAP money in terms of increased sales and procedures. Such ROI is often used as a reason to renew a particular LAP fund to a provider.

95. The program primarily targets providers who treat Uterine Fibroid Embolization "UFE" (on-label for Embosphere). UFE appears to disproportionally affect African American women between the ages of 25-50. Demographically, that group tends have a higher representation in the Medicaid program. The group is also treated in VA hospitals. Merit specifically targets African American women in these groups.

96. For example, Merit targeted the "best performing UFE group in Indiana" to contribute to its social networking campaign, targeting women searching Google for "UFE" or "fibroids:"

> **From:** Bucky Horn
> **To:** Jim Heyd
> **Subject:** LAP for Community
> **Date:** Wednesday, November 12, 2014 12:38:57 PM
> **Attachments:** LAP IRV 2014.xls
> Hey Jim;
> Here's the LAP form for Community. As we discussed, Karen Ehrman came to me asking to help financially in a hospital promotion for UFE.
> The hospital asked the IR group to contribute to a targeted Social network campaign. The hospital asked them for $1800/month for 6 months, and she asked if we would help contribute.
> This is the best performing UFE group in Indiana, they have done 31 so far this year with more on the schedule. They have spent $50,000 on Embospheres this year, as well as a couple Quadrasphere cases.
> I would like to submit this LAP for a donation of $1000 to offset their contribution to the hospital's promo campaign. It seems very similar to our microsite program, but will send FB ads to likely UFE candidates or those who google 'UFE' or 'Fibroids'. The group already has a pretty comprehensive website, with doctors speaking about UFE and other procedures.
> http://www.irvingtonradiology.com/
> Thanks for your help, let me know if you need more info.
> Bucky

97. Through efforts like this, Merit has steadily increased its yearly Embosphere revenue and did $30 Million in Embosphere sales in 2014.

98. Though funded by Merit, most of the LAP advertisements do not mention Merit or note any relationship with or contribution by it. Upon information and belief, the patients are never told of the payments Merit makes to the providers to induce the use of its devices.

99. As an example, in 2013, Merit sales representative Kevin Shirley brokered a deal with medical provider, Baptist Medical South. Shirley received approval from Merit (Keenan Holbert, Regional Sales Manager) to purchase ads over a four-month span for Baptist.

Merit paid half and the provider paid half of the cost of the ads. An email between the sales representative and sales manager dispels any notion that this payment is educational. The email notes that if this radio advertisement money is paid for this provider, these Merit employees will both make "the president's club" (a Merit sales reward club for the highest performers), meaning that this ad money will pay a direct return to Merit in terms of future sales:

From: Kevin Shirley
Sent: Friday, May 03, 2013 10:12 AM
To: Keenan Holbert
Subject: Re: LAP for UFE ads in Montgomery

I think that is correct- I will get a copy of the ad.
*per our last conversation- you still had all of your UFE budget with no plans of anyone using it. Has that changed at all?
I promise that the money we spend will come directly back in UFE business
and help us both make presidents
club (hopefully)...Baptist is a VERY good UFE program with lots of resources dedicated to this business segment. I will take you down there to meet everyone on your next visit.

This is also the same group that I converted to the ONEsnare a month or so ago and have eval's starting next week for the drainage products. Dr. LeQuire is a good friend and a wonderful guy.

I just hope and pray we can get this approved...? I've been promising him radio money for the last 6 months.
Thanks so much for your efforts!!
Have a great day and weekend!!
KS

Kevin Shirley
Merit Medical
(205) 383-9980 cell
kshirley@merit.com

100. The "UFE" program noted in many of the LAP emails references Uterine Fibroid Embolization. Merit's Embosphere devices are indicated for the embolization of uterine fibroids (#K021397). In other words, these Merit-funded advertisements directly intend to influence the provider's choice of device to treat uterine fibroids without informing the public and the patients that the provider's choice has been unduly influenced by the payments from the manufacturer.

101. Internal emails demonstrate that Merit's goal is to influence the provider's choice of manufacturer by paying for its advertising, as can be seen in the last line of the following email, "I KNOW this will help produce an increase in embo sales:"

From: Kevin Shirley
Sent: Friday, July 19, 2013 4:24 PM
To: Keenan Holbert
Cc: Kevin Shirley
Subject: RE: LAP for UFE ads in Montgomery

Here you go.
I finally got this thing carved out to fit our money that you suggested we do at this time. I actually ended up spending less than the $1,125 per month for 4 months that you suggested. With this current format, it will only cost us $4,275. Baptist South will kick in the other $4,275. And this will run us through the end of the year. That is the wonderful part!!

I also have attached both radio adds that we have been using for the past 3 years in Montgomery. Let me know if you think we need to change or if we have a different radio script that you feel is more effective and I can get the radio folks to record it for me. Hopefully this will help us finish the year strong with embo!!

1

Finally, I went ahead and just did a new LAP form, even though you had already approved the former one I sent to you. This way all of the dates will be current. You should have everything here that you need to get us on the air with this effort.

THX for all of your help on this matter!! I KNOW that it will help produce an increase in embo sales.
KS

Kevin Shirley
Sales Representative

Mobile: (205) 383-9980
Fax: (801) 316-4862
Email: kshirley@merit.com
Customer Service: 1-800-35-MERIT

102. To justify the ad buy to his regional manager, two times in the above email, the sales representative notes that paying for this radio advertisement will increase Merit's device sales for Embosphere ("embo"). The intent by Merit to influence the purchase and use of Merit

devices by paying for provider advertising is clear. The resulting ROI is also clear, and is used to justify spending even more advertising money for providers.

103. The LAP is also used to gain or convert providers to use other Merit devices, such as QuadraSphere. There was an intentional goal of getting in the door through Embosphere and then "pulling through" Merit's other devices, including QuadraSphere, Maestro and others. As such, Embosphere acted as Merit's gateway device for subsequent and varied device sales, all of which are tainted due to the kickbacks. Sometimes this was accomplished through bundling as when a customer purchased Quadrasphere, they received a free Maestro catheter to also get that product in the door.

104. The kickbacks go beyond Embosphere. For example, Dr. J. David Prologo (of University Hospitals Case Medical Center in Ohio) was given a $5,000 research payment in the spring of 2012 with the intent to have him present and get coveted "podium time" at a CME event (*i.e.,* SIR 2012). A physician is not supposed to be influenced by the industry for a CME event, but Merit paid him $5,000 to give this prestigious CME presentation and to buy his loyalty and influence his remarks.

105. LAP funds are also used to pay for physician dinners. A $600 Merit-sponsored dinner for Dr. Fischer (Kaweah Delta in California) on March 27, 2014 was approved as he was giving a talk on TACE and had ordered Merit products "out of good faith." In the LAP approval form, the sales representative wrote:

> Dr. Fisher was approached by Boston Scientific to give a talk promoting Contour SE, UFE and cTACE. Fortunately, Boston Sci canceled support of dinner and Dr. Fisher turned to Merit Medical. **They are ordering a stocking order of Quads, Maestro and Chemo delivery kits out of good faith.**

(Emphasis supplied). In addition, the accompanying email request for approval justified the spend by noting that the physician is converting and expanding his Merit product use:

> Good evening. I would like to approve this small Dinner directed toward Oncologists. Cost approximation would be around $600. **The physician is looking to enhance his referral pipeline planning to convert to Quads, maestro and try out our medication delivery kit.** Thanks.

(Emphasis supplied).

106. This LAP money immediately resulted in ROI as tracked by Merit. One email on April 10th had the subject: "**Kaweah came thru...ROI for a dinner,**" and stated in part:

> FYI. This is new business from Dr. Fisher. He is the new up and comer IR that did a talk a couple weeks ago directly to local oncologists to try to build his pipeline referral base for chemo embo's.
> 4 vials of quads/3 Maestros. Good start.

107. A later email on June 17, 2014 again followed up on the Dr. Fischer LAP ROI and noted that the first case (patient) was scheduled:

> Hi Brian,
> Kevin [Sterba] has asked me to follow up with the reps who have participated in the LAP program to see what kind of ROI they have seen from their particular event.
> Have you seen any increase in orders as a direct result of the Dr. Fisher Oncologists Dinner that was held in March? What dollar volume have you seen?
> Any information that you can send me will be helpful. **We are trying to determine what type of events are giving us the biggest bang for our buck.**
> Thanks!
> Alaine

Brian Oleson responded:

> Alaine,
> I have great news on our ROI from Dr. Fishers talk to Oncologists. After our dinner, Kaweah Delta placed a stocking order and we have our first case next Thursday.

5915207__V325QS	QUAD	Interventional	1,550.00	3,100.00	2	4/10/2014 10:00 AM
5915207__V225QS	QUAD	Interventional	1,495.00	2,990.00	2	4/10/2014 10:00 AM

Thanks for the support, the LAP was essential in educating DEB TACE to local Oncologists.
Brian

108. In another example, in 2013, Merit paid $1,600 for a radio ad for Lakeland Regional Medical Center. The email from the sales representative, Brian McClish, notes that this provider uses Merit's Embospheres "exclusively" and that with Merit's help, this provider should be able to get back to "10+ procedures/month." To justify the ad buy, he also notes that the practice also uses QuadraSpheres ("QS"). The sales representative also notes that the ad buy from Merit will yield greater purchasing of Merit products from this provider, "our commitment to his practice should insure a QS/Maestro bundle this quarter."

From:	Brian McClish
Sent:	Monday, February 11, 2013 10:50 AM
To:	Local Ad Process
Cc:	Rod Ferrand
Subject:	Local Ad Process - LRMC
Attachments:	LAP Form LRMC.xls

Good afternoon,
This is a great account that gets out into the community to promote UFE and uses EmboSpheres exclusively. They have requested my help again after tremendous success and growth during my time at BioSphere. Their UFE's "dropped off the map" upon my departure from BioSphere and we are excited to get them back to their proper volume of 10+ procedures/month. Dr Elmasri is seriously considering using QS, and is currently using LC Bead, RF Ablation, Microwave, Cryo, Lipiodol...our commitment to his practice should insure a QS/Maestro bundle this quarter.
There should be some trickle over to ORMC in Orlando as a result of this campaign as well, from my experience.

Brian McClish
Sales Representative

Mobile: (813) 416-7625
Fax: (801) 826-4184
Email: brian.mcclish@merit.com
Customer Service: 1-800-35-MERIT

109. In both of these examples, the sales representatives note that the providers are accustomed to the company paying for their advertising because that is how it was done with Merit's predecessor, Biosphere.

110. QuadraSphere and Embosphere were developed and originally distributed by BioSphere Medical, a company Merit acquired in September 2010. Merit intentionally and strategically continued some of the tactics employed by Biosphere, including the off-label marketing and promotion and kickback allegations made herein and the LAP payments. It chose to adopt, continue and expand on many of these practices. Moreover, some of the same personnel continued on. For instance, Jim Kelly was a director of marketing who worked for Biosphere before the acquisition, stayed on with Merit after the acquisition, and whose name appears on many internal emails approving LAP funding for high-volume Merit physicians.

111. In another internal email, Merit discusses gaining valuable entry into the VA hospital market for its Quadrasphere ("QS") devices and using money in its budget to sponsor events that will lead to more off-label use of QS in these hospitals. It also summarizes that, "to put this opportunity into perspective, we could be looking at north of 20 new Quad cases per month equating $26K +/- of new monthly business…":

From: Giovanni Crovetto
To: Kevin Sterba; Keenan Holbert
Cc: Antonio Rivera; Jesse Hansen
Subject: FW: Dr Raj, Dr Bhatia Synergy Meeting
Date: Tuesday, August 05, 2014 6:12:11 AM
Attachments: EXHIBITOR-PROSPECTUS-SYNERGY-2014-FINAL-PDF-05.06.14-with-fields.pdf
Synergy 2014.pdf

Hello Kevin.

Hope all is well.

As you are aware, the Synergy meeting is fast approaching (mid-November) and we have to make a decision very soon.
While I understand our budget has been drastically reduced, this is one meeting we can't afford to pass. For us, this is a huge opportunity as we have recently introduced QuadraSpheres at the VA Medical Center with Dr. Bhatia and have completed 4 great cases with many more to come. Btw, Tony, Dr. Bhatia and I review the first Quad case CT study post 4 weeks and the response rate was great with much less pain when compared with LC Beads treatment.
Dr. Bhatia and Dr. Narayanan (a.k.a. Raj) University of Miami Chief IR Director are part of the same group. The reason this is important to understand is that Raj is also the Synergy Program Director. While Raj has not used QuadraSpheres yet, he is closely looking at Dr. Bhatia's (VA Medical Center) results and would likely shift some cases our way once he is convinced Quads offer better benefits than LC Beads and Y-90. Dr. Bhatia and Raj both are now helping us bring our Quads to Jackson Memorial and we will then work on UM Hospital as well as UMHC once the result are out. To put this opportunity into perspective, we could be looking at north of 20 new Quad cases per month equaring $26K+/- of new monthly business once we add the rest of the hospitals.

Tony, Jesse Hansen and I met with Raj and Dr. Bhatia to discuss the Synergy meeting and we learned attendance has been increasing year after year. As a matter of fact, last year's attendance was 400+ people and he expects an even better attendance for 2014. As for faculty, it is staffed by national as well as international leading experts in HCC, Lung Cancer, Mets, Cholangiocarcinoma & Liver Cancer, Renal Cancer, Prostate Cancer, Neuroendocrine, Musculoskeletal Tumors as well as Palliative treatment options. (See attachments)

http://synergymiami.org/

As Tony mentioned in the below email, the upside is huge with a small investment. Fees start at $3K for a 10X10 booth. Std. placement & 2 complementary entrance tickets (Floor access only) followed by what I would suggest $5K Premium placement 10X10 booth with 3 complementary entrance tickets (full access to sessions and food functions) and lastly $10K with a 10X20 booth.....
I would be more than happy to handle the setup, tear down and to man the booth with Tony to minimize our expense.

In advance, I really appreciate your consideration supporting this meeting and please let me know if you have any questions.

Sincerely

Giovanni Crovetto
Sales Representative
Interventional Division
Mobile: (954) 439-5506
Fax: (801) 316-4889
Email: Giovanni.Crovetto@merit.com
Customer Service: 1-800-35-MERIT

112. The above email shows Merit's desire to use LAP funds to sponsor a meeting in order to increase its footprint in the VA hospitals and to induce those doctors to use its devices and products.

113. Merit has editorial control over the LAP advertisements. The advertisements do not typically mention Merit's name, affiliation, contribution or relationship to the provider. A sample advertisement, this one for Charlotte Radiology group, was published as follows:

COPY/SAMPLE

CLIENT: Charlotte Radiology A.E:

START: STOP: LENGTH: 60 Second STATION:

10

WomenLadies, I've got 60 seconds to talk to you about your uterus and uterine fibroids. If you're one of the many, many women who are listening and suffering from heavy abnormal bleeding and pelvic pain caused by fibroids, *you are not alone.* You deserve to know about a proven alternative that helps alleviate the pain.

Uterine Fibroid Embolization, or UFE, is a non-surgical, minimally invasive treatment option offered by the experts at Charlotte Radiology. It's covered by most insurance plans, requires a one-night hospital stay and will have you back to your normal routine in about one week.

UFE is a successful treatment option for *thousands* of women with no surgery, no general anesthesia and best of all, you get your life back!

30

Don't let fibroids ruin your life. Schedule a consultation with Charlotte Radiology by calling 704.FIBROID. That's 704.F-I-B-R-O-I-D.

45

60

DOUBLE SPACE ALL COPY • ALL NUMBERS MUST BE TYPED OUT IN "ALPHA" • NO ABBREVIATIONS

MR12-078 Rev. A

From: Brian Anthony McClish
Sent: Wednesday, April 22, 2015 1:26 PM
To: Local Ad Process; Keenan Holbert
Subject: Gospel Radio Tampa

All,

I uncovered an excellent opportunity to earn some additional UFE business for my old buddies at St Joseph's Hospital in Tampa and get the new facility off the ground down in Sun City Center! Please find attached an LAP and Proposal/Invoice from a local radio station in Tampa Bay. Dana has been answering the phones and handling patient consults and scheduling for close to 10 years, so they are ready. Thanks!

Brian Anthony McClish
Merit Medical Systems, Inc. Interventional Division
(813) 416-7625 cell
brian.mcclish@merit.com

118. LAP funds only get approved if the provider is a current customer or a likely future customer. In one internal email, a doctor is asking for a price break on Embospheres. The Merit sales representative responds that they cannot give him the price break he is looking for, but they have other ways to drive business to his practice, a reference to the LAP funds:

> On Dec 23, 2014, at 11:01 AM, Bucky Horn <rhorn@merit.com> wrote:
>
> Dr Hong;
> Thanks for your interest in Embospheres. We would love to have your embolic business, but GPO constraints prevent us from lowering our price to Embozene levels. We do, however have **several programs that can help drive UFE business to your practice** that I would like to discuss with you.
>
> Would you be available to meet and discuss how Merit might partner with your group to increase UFE procedures?
> Thanks and have a Happy Holiday!
> Bucky

(Emphasis supplied).

119. In discussing the LAP funds for this provider, the Merit sales representative tells his superiors that this doctor **will get removed** if he doesn't convert to Merit:

> On Dec 23, 2014, at 11:31 AM, Bucky Horn <rhorn@merit.com> wrote:
>
> He was asking me about reconstituting Embosphere like a Dr Hogg does at NW. I texted Matt about it, and he
> was unaware of any special thing.. Then Hong contacted Hogg and said they were using 2ml vials...
> Vials were $10 more than syringes...
>
> This is a real opportunity, but the account is a royal pain to me.. this is the IR PD account as well as the failed
> Worley account. Hopeful to speak with Hong soon.. I have them on ASK4UFE, **but will remove them if they don't convert...**
>
> Bucky Horn
> Sales Representative
> Interventional Division

(Emphasis supplied).

120. This threatened "removal" of Dr. Hogg is a specific reference to Merit's online physician referral service. Merit hosts and sponsors a "public education campaign" with a website at www.ask4ufe.com. While on the surface, this appears to be a simple public education campaign, behind the scenes are hidden kickbacks.

121. Merit's website, www.ask4ufe.com, is a referral service for physicians treating UFE. However, *only* Merit customers or demonstrated prospective customers are allowed to be on the website's referral list. Merit's sales/marketing division gets the ultimate say about which doctors to include, exclude and remove. There is no independent or objective criteria for inclusion or removal. Moreover, if physicians do not demonstrate Merit loyalty, as the above email demonstrates, they are removed from the referral service altogether. Thus, there is a blatant *quid pro quo* at play and this referral service does not qualify for safe harbor under the

Anti-Kickback Statute. If physicians use Merit devices, they are included in this referral site, which Merit actively markets and supports. Interventional Radiologists are more dependent on referrals than others. So, inclusion in this referral service is a benefit to them. Then, when they are included in the service, the expectation from Merit is that they will continue to use Merit devices and increase Merit's sales, or else face removal.

122. In another example of the *quid pro quo* or conditional nature of the LAP money, one Merit manager approved $2,000 to Augusta Vascular only after Merit discussed with the provider "the use of competitive products by his partners:"

Teresa Johnson

From:	Mark Owens
Sent:	Wednesday, August 01, 2012 12:18 PM
To:	Local Ad Process
Cc:	Melody Carithers
Subject:	FW: LAP form August Vascular
Attachments:	LAP 2012 Radio Augusta Vascular.xlsx

Okay, based upon a conversation I had with Melody today I am approving this request. Melody will be contacting Dr. Riggins about the use of competitive product by his partners.

If I'm not mistaken YTD we've sold 4 boxes of ES to this account at $975 or $195 per vial. We will measure this volume after moving forward with this radio campaign. I've added an appointment in my calendar for the end of the year.

Serve to lead and lead to succeed,

Mark Owens
Manager, Regional Sales

Mobile: (804) 334-7543
Fax: (801) 208-3387
Email: mowens@merit.com
Customer Service: 1-800-35-MERIT

123. In another typical funding exercise by Merit, it drafts, pays for and distributes referral letters for Embosphere users to attract referrals to them from other physicians. Many of these letters note that Medicare reimburses for the UFE procedures. Merit typically pays about $1,000 for each mailer, with the intent to induce referrals to the physician and thereby increase its own Embosphere sales. Nowhere on the letter does Merit's name, affiliation or payment appear. According to internal emails, one such letter in 2014 for Dr. Delbrune read:

> Dear Doctor,
> I would like to take this opportunity to familiarize or reacquaint you with the **Robert Packer Hospital's Uterine Fibroid Embolization (UFE) Program**. This procedure is being offered as a minimally invasive alternative to treat abnormal bleeding, cramping, and mass induced symptoms (urinary frequency, pelvic pain/fullness) due to uterine fibroids.
>
> Our technical success is 100% and our clinical success is around 90%. These results are very similar to large multicenter studies which have shown approximately 90% clinical improvement of abnormal bleeding and mass induced symptoms.
>
> All patients referred to me receive a full consultation prior to scheduling any procedures. Typically they will also have an MRI, Pap smear, and an endometrial biopsy (EMB) in certain older patients. Some patients will also require a hysteroscopy and/or laparoscopy for further evaluation.
>
> If the patient is deemed a candidate for UFE, they will be admitted to the interventional radiology service the day of the procedure. UFE is performed under minimal sedation and takes 1 - 2 hours. Following the procedure most patients are discharged within 23 hours. Abdominal pain and nausea are common following the procedure and are typically easy to control. These symptoms decrease over the first 48 - 72 hours and most patients return to normal activity in seven days.
>
> UFE is covered by Medicare and private insurance companies. All patients are precertified by our office. Please contact my office in Interventional Radiology Scheduling, to schedule UFE consultations: **(570)-887-5599**. Also, please call

> if you would like additional copies of the enclosed UFE patient education brochures for your office.
>
> Over the years, UFE has proven to be an effective and safe therapy for symptomatic fibroids. It is not for everyone. If you have any questions regarding the procedure, patient selection, or outcomes, please call me at: **(570) 887-5599.** I will be happy to speak with you.

124. Though Merit paid for and published this ad, the sole phone number provided is that of Dr. Jean Delbrune, for whom the letter was written. The only comment and edit was that this could not go on the hospital's "official" letterhead. Otherwise, it was approved as is. Merit's name appeared nowhere on this mailer and no one can tell from looking at it that Merit paid for this and expects a return on its investment from it. This is but one example of mailers paid for and distributed by it to market referrals directly to Merit's high-volume user physicians.

125. Another aspect of Merit's LAP program is an improper kickback scenario wherein Merit pays for items other than traditional advertising for providers to induce and increase referrals and increase sales of Merit devices.

126. For example, the LAP program has been used to pay for sporting event tickets for provider groups such as the Cooper Health Physicians in Philadelphia. In another example, Merit LAP funds in the amount of $1,500 were used to sponsor a dinner for physicians with the express goal of increasing doctor referrals for his UFE practice (and thereby increase Merit's Embosphere sales):

114. Merit paid $5,000 for the above advertisement. The internal Merit emails approving this ad buy demonstrate that Merit had editorial control over its content.

115. They also confirm that the provider would not run the advertisement unless and until Merit contributed.

116. Another example of the LAP payments relates to Chesapeake General Hospital, where Merit spent $10,000 for the providers' UFE marketing program. To justify this spend, Merit noted the hospital's precise volume purchase of Merit devices the year prior, totaling over $300,000:

> Jim
> I spoke with Dianne about Chesapeake General Hospital (account# 6795) today. In the past, we have contributed ~10K to their UFE marketing programs. I'm requesting that we do the same this year. **In 2013, they purchased 62K in Embo Caths, 228K in Embosheres and 16K in Meastros.** Please let me know your thoughts.
> Thanks
> Tim Dempsey
> Sales Representative
> Interventional Division

(Emphasis supplied).

117. In a similar example, a sales representative notes the opportunity to expand Merit's business in the Tampa area by funding St. Joseph's Hospitals' UFE ads ("I uncovered an excellent opportunity to earn some additional UFE business.") Merit paid $3,000 for this at the sale's representatives' urging:

Hello,

Please find attached an LAP form for Dr. John Fischer. We will be hosting the OB/GYN's group from the Kelsey Seybold Clinic of Houston. This is one of the largest OB/GYN practices in Houston and we're expecting over 30 Physicians there to hear Dr. Fischer speak on UFE. Our goal is to expand his referrals within this group.

The funds will assist with the dinner for this meeting.

Thanks,

Justin Arnoldi

Justin Arnoldi
Sales Representative
Interventional Division

Mobile: (713) 594-7687
Fax: (801) 316-4863
Email: jarnoldi@merit.com
Customer Service: 1-800-35-MERIT

127. LAP money also pays for catered events attracting or rewarding Embosphere customers. In one internal email, the sales representative touts catering an event for 20 physicians that are a "100% Embosphere house" and a "potential QS conversion," referring to QuadraSphere:

From: Brian McClish
To: localadprocess@merit.com
Cc: Keenan Holbert
Subject: OB/Gyn Luncheon this week
Date: Sunday, July 06, 2014 5:03:00 PM
Attachments: LAP Form LRMC OB-Gyn Lunch 07-08-14.xls

Hello,

I've planned a big luncheon for a large OB/Gyn Group in Brandon, FL (20 providers) on behalf of Lakeland Regional Medical Center and South Florida Baptist Hospitals. The IR group associated with LRMC is trying to build business at SFBH and initiate a fibroid center. **They're a 100% EmboSphere house and still a potential QS conversion.** Just continuing the relationship

> and staying in front of them with our value ad and practice building effort. Thanks!
> Brian Anthony McClish
> Merit Medical Systems, Inc. Interventional Division (813) 416-7625 cell
> brian.mcclish@merit.com

(Emphasis supplied).

128. Merit also pays for golfing outings paid for by the salesforce to attract or get physician customers. In its budget, Merit keeps a column for this called "activity support" which is defined in the spreadsheet as "golf."

129. The LAP payments and other payments alleged herein were in reality a *quid pro quo* to increase the purchase of Merit devices.

130. In fact, LAP payments were made at the initiation and discretion of sales representatives with management's encouragement, knowledge, endorsement and express approval. LAP payments were based entirely on past sales or future sales potential, and were totally irrespective of fair market value of the services provided. Merit carried on this sham "grant" or "educational" program with the specific intent to induce sales of its devices.

131. In summary, Merit systematically pays kickbacks to physicians with the intent to induce the use of Merit devices paid for by Federal and state health care programs. Merit has violated the Federal Anti-Kickback Statute, 42 U.S.C. §1320a-7b and similar state statutes, by, *inter alia*, offering and providing illegal remuneration to physicians in the form of marketing and advertising dollars, speaking fees, dinners, trips, writing fees and other cash, as an inducement to use its devices both on and off-label. In addition to the kickbacks paid specifically to high-volume Merit device users, Merit has engaged in systematic kickback payments to physicians to induce the use Merit products and devices. This includes consulting fees paid even though no work is performed and Merit-sponsored lunches and dinners wherein

Merit pays the speaker fee, pays for the meals for the attendees and where the speaker discusses off-label uses of Merit devices including QuadraSphere and Embosphere.

132. Though Merit did have some written agreements with some LAP provider recipients that state that the money is not to be considered a kickback or influence choice in treatment or devices, the internal emails confirm that the written agreement is just to comply with legal requirements and so as not leave a paper trail. One email expressly lays out the scheme, then notes that the *quid pro quo* is "**not to be linked on paper**:"

Sent: Thursday, April 21, 2011 9:21 AM
To: Monroe May; Judy Kirk
Subject: Main Line Health
Monroe,

Main Line Health is a four hospital health system in the most affluent part of Philadelphia. The hospital system does not offer chemoembolizations as a course of practice but they are gearing up to incorporate this therapy into their practices. Last fall I spoke to Fred on the phone and mentioned my desire to offer the system an unrestricted education grant for an Oncologist from Northwestern to come into the system and speak about the effectiveness of drug loaded chemo embolizations. Fred said at the time that it seemed like a "no brainer". He asked how much money would be needed and I said I am not sure but probably around $5000 or so.

The system recently added a doctor from an outside hospital who has done chemo embolizations. They are also adding one more IR doc that is coming from Northwestern in the next few months and he will head up the Oncology side of the business. In short the opportunity to align ourselves with this system is very near and I wanted to ask for your approval to offer the system $7500 for an Unrestricted Educational Grant (which would fund the meeting referenced above). $7500 may be a little more than is needed but it will ensure we cover the expense of the meeting completely. The one caveat here is that the new doctor and the doctor from Northwestern have used LC Bead and have not tried Quadrasphere. However, my hope is we can help them get the system moving in the drug loading embolization direction with this grant and position ourselves to be the vendor of choice when the time should come.

I can tell you that I have spoken to all four primary IR physicians and they are all hopeful and very appreciative of our efforts to consider such a grant. Please let me know your thoughts? If approved I will likely need to have the grant letter generated on our end because the doc heading up this request is extremely busy and very much a

procrastinator. However in the end if things go as I hope the $7500 will be a very small contribution to the overall potential (**even though the two are obviously not to be linked on paper).**

Tony Decant
Sales Representative

Cell: (609) 221-7957
Fax: (801) 253-6983
Email: adecant@merit.com
Customer Service: 1-800-35-MERIT

MERIT MEDICAL | BioSphere Medical
www.merit.com www.ask4ufe.com

(Emphasis supplied).

13. Though the *quid pro quo* inherent in the LAP program is obvious in verbal communications and internal Merit emails, internal management and sales force understand that it cannot be "linked on paper" so as to avoid detection as the kickback that it is.

134. By paying remuneration to providers as a *quid pro quo* and to induce the continued use of Merit devices or the conversion of providers into loyal Merit customers, Merit tainted all of the subsequent claims submitted by those providers for Embosphere and all other Merit products.

135. Another way in which Merit rewarded physicians and continued to ensure that its products received favorable print coverage in journals and studies was and is to fund studies for loyal Merit physicians, who have a demonstrated bent towards Merit products and who spin the study's results in Merit's favor.

136. In one example of the internal thought and decision-making and the consideration of past purchases of Merit product to effect Merit funding of a study, a sales representative pushes for a Merit-funded study for Dr. Alan Cohen after his Merit superior receives Dr. Cohen's Merit use and financial numbers. The sales representative wrote in part:

> In regards to our phone conversation. Dr. Cohen with Memorial Hermann has expressed numerous times his interest in pursuing a head to head clinical trial of LC beads vs. Quadraspheres. **He feels this will support determining what product should be his first line treatment for his HCC patients**. He also wants to see additional US data presented on Quadraspheres. With data starting to release on the Sirtex Sirflox trial in their potential push of y-90 as a first line treatment it is important that we get aggressive in presenting data supporting Quadraspheres as a baseline treatment for HCC.

(Emphasis supplied). The Merit senior product manager then responded:

> SIRFLOX is for first line treatment in mCRC.
> Thanks for the info.
> **Can you give me some numbers and potential business there. Money numbers, as you know, go a LONG way!**
> Thanks Justin, this will help tremendously.

(Emphasis supplied). The sales representative responded:

> Hermann numbers. They treat on average 10-15!HCC cases a month. Using y90, beads and Quads.
> Potential overall annual revenue: $312k-$468k/yr.

137. In another example written on March 20, 2015, Merit's sales department discusses fast tracking a study that will be favorable to Merit given its recent investment in the affiliated hospital:

> Marty,
> In follow-up to our meeting earlier today, it seems that Philippe Reb will be able to perform a bench study of contrast behavior in HepaSphere/Quadrasphere fairly quickly. While that is proceeding, we will organize an in-vivo study with HepaSphere/QuadraSphere in animals at Johns Hopkins. Dr. Weiss ("GAE Dr. Weiss") has agreed to take the lead on helping us move this project to completion as swiftly as possible. **Given Merit's investments in Hopkins' projects recently, I'm sure he'll continue to be as good as his word.**
>
> I'm working up a project plan for review by Curt, Philippe and Dr. Weiss. I'll give you an update sometime Tuesday next week on timing, etc.
> More to follow,
> Jim

(Emphasis supplied).

Consulting Fees and Lavish Vacations

138. Merit pays consulting fees paid to providers, many if not all of which are for little-to-no work performed.

139. For example, Dr. Mark Garcia (an interventional radiologist from Delaware) is a long-time "consultant" for Merit who has received $4,000 a month in "consulting fees" though no work is performed for this payment. In 2014, he was paid $4,000 every month for no work. He also received about $7,000 that year in royalties paid by Merit.

140. Similarly, Dr. John White received $1,000 per month as a flat fee. No work was required in order for Dr. White to receive this consulting fee. When he did perform work, for example, a lecture or training class, he received an additional $1,000/lecture or training class in the Salt Lake area and $1,500/classes outside of Utah, further proof that the retainer was for loyalty and use of Merit products and not for actual work.

141. Other physicians on monthly or yearly retainers in 2014 and 2015 included: Dr. Bolia (£10,000 British Pounds annually); Dr. Jean-Pierre Pelage (€10,000 per year, paid quarterly); Dr. Peter Hathaway ($2,000 per month); and Dr. Jeffrey Siegel ($2,000 per month). These physicians had written consulting agreements with Merit, which were a sham.

142. While many of these sham consulting agreements are documented in an attempt to appear legitimate and in an attempt to fit into the safe harbor regulations of the anti-kickback statute, they in reality were not legitimate and do not quality for safe harbor.

143. The written agreements require the consultants to submit invoices with detailed work performed, but none ever did because they did not perform actual work. They were paid regardless. Instead, these monthly consultant fees were to induce or reward those physicians

who used Merit products and to induce them to promote Merit products to other physicians, thus disqualifying them from any safe harbor.

144. Moreover, if any work was actually done, the consultants would get more than their monthly retainer, further evidence that the monthly retainer was not for services rendered, but simply to reward and keep brand loyalty since actual work was always paid on top of the monthly or yearly retainer payments.

145. Fred Lampropoulos, the Chairman and CEO of Merit, was personally involved in and almost always had the final say as to which physicians became consultants. A physician's ability to drive Merit product was always taken into account when considering making them a paid consultant, as were the physician's previous use and financial numbers for Merit products.

146. Below is an example of a representative presentation made to management for a potential consultant:

> Dr. Hoffmann (Fee-for-service consultant to Merit)
> Participated in US Sales Meeting January 2014 as instructor on embolic procedures
>
> Winthrop Hospital, Mineola NY ()
>
> EmboSphere Monthly Revenue Jan 1, 2013-present
>
> QuadraSphere Monthly Revenue Jan 1, 2013-present
>
> All Other Products Monthly Revenue Jan 1, 2013-present

Proposal:

- Facilitate Dr. Hoffmann to visit the Merit facility in Roissy to observe how Merit's embolics are made
- Facilitate Dr. Hoffmann to visit Merit KOLs in metro-Paris during the same time period to observe embolization procedures

Merit Requirements

- Merit will sponsor Dr. Hoffmann's Flight (~$5,000 business class)
- Merit will sponsor Dr. Hoffmann's Hotel during this visit (~$2,000; 5 nights; $400/night)
- Merit will provide Dr. Hoffmann a formal letter that describes the visit
- Merit will establish an itinerary that includes visitation time with Roissy Operations/Manufacturing; Roissy R&D and KOLs in the Paris area (likely Marc Sapoval)

Dr. Hoffmann Requirements

- Dr. Hoffmann will be responsible for attending all scheduled meetings on time

Benefits to Merit

- Elevated relationship with Dr. Hoffmann
- Increased understanding of embolic manufacturing process in order to facilitate more insightful instruction to sales reps and during consultations with other physicians where Dr. Hoffmann is the consultant
- Feedback/insight into unmet needs regarding embolics and embolization procedures

Benefits to Dr. Hoffmann

- Elevated relationship with Merit
- Elevated relationship with KOLs
- Added insight into embolization procedures

147. As evident, Dr. Hoffman's QuadraSphere and Embosphere revenue and how it relates to his other (non-Merit) revenue is the top consideration in this presentation to management. This proposal also included sending Dr. Hoffman (a "KOL," Key Opinion Leader) to Paris ostensibly to tour a facility, but really it was to reward him for loyalty and to pay for him to mingle with other Merit KOLs.

148. The consulting fees paid to these providers were not for actual services rendered. They were a kickback meant to induce providers to use Merit devices to the exclusion of others and to pay for these KOLs to promote Merit products in the medical community. The monies paid to these providers taint all of their claims for Merit devices to government payers.

149. In another way to drive revenue and reward physician loyalty, Merit uses its President's Club as a benefit not only for its highest sales representatives, but also as rewards for loyal Merit physicians. The President's Club vacations were always in attractive locations. The 2010 vacation was in the Bahamas, 2011 was in Bahamas, 2012 was in Kona, Hawaii, 2013 was in Puerto Rico and 2014 was in Maui, Hawaii.

150. Over Relator's objections, Merit paid for physicians to attend the President's Club under the guise of education, which if at all, was a one-hour speech. In 2013, Dr. Pete Hathaway, Dr. Jeffrey Siegel and Dr. Seth Worley attended the President's Club vacation, all expenses paid by Merit, in Puerto Rico. Drs. Hathaway and Siegel were long-time Merit physicians who had been paid consultants since at least 2012 and continuing to today. In 2014, Drs. Stephen Ash and Ayad Agha attended the President's Club paid vacation to Maui.

151. Additionally, physician spouses and children were welcomed to attend the President's Club. While airfare was not always covered for spouses (though Relator was told that sometimes it has been), spouses and family were openly invited to Merit-sponsored receptions, happy hours, lunches, dinners and the gala (all food and beverage covered by Merit for spouses and families of physicians). In addition, upon information and belief, each physician was given a *per diem* to cover other food for his whole family on the trip.

152. According to internal expense reports, in 2014, Merit spent almost $30,000 on the President's Club and some $704,811.81 on "entertainment" expenses spent on physicians.

153. Merit's entertaining of physicians extends beyond the United States. Merit routinely wines and dines physicians and funds expensive trips for physicians who practice in

foreign countries and regions, including Brazil, China and Russia. These physicians predominately meet the FCPA's broad definition of "foreign official," because they are decision-makers and healthcare is publicly-funded in these countries and regions.

154. Per the Department of Justice, the Foreign Corrupt Practices Act of 1977, as amended, 15 U.S.C. §§ 78dd-1, *et seq.*, was enacted to make it unlawful for certain classes of persons and entities to make payments to foreign government officials to assist in obtaining or retaining business. Specifically the anti-bribery provisions of the FCPA prohibit the willful use of the mails or any means of instrumentality of interstate commerce corruptly in furtherance of any offer, payment, promise to pay, or authorization of the payment of money or anything of value to any person, whilst knowing that all or apportion of such money or thigh of value will be offered, given or promised, directly or indirectly, to a foreign official to influence the foreign official in his or her official capacity, include the foreign official to do or omit to do an act in violation of his or her lawful duty, or to secure any improper advantage in order to assist in obtaining or retaining business for or with, or directing business to, any person

155. At times, physicians are sent by Merit to foreign countries as a reward for loyalty and as an inducement to use Merit products both on and off-label. These trips are meant to, and do result in, Merit products "breaking into" foreign markets by inducing the decision-makers to choose Merit over the competition in their hospitals and regions.

156. For example, Merit attempted to influence Chinese doctors by sending them on a Merit-funded trip to Lisbon, Portugal and then on to Paris, France on or about September 15-20, 2012. The doctors included: Dr. Zhong Hongshan from the First Hospital of China Medical University; Dr. Li Huai of the Cancer Institute & Hospital; Dr. Yang Ning of the Peking Union Medical College Hospital; and Dr. Zou Yinghua of the Peking University First Hospital.

157. These were papered as "educational grants" under Merit's "corporate social responsibility" to educate physicians. The sham "cover" was for them to go to Merit's facility in Paris for a very short tour. The tour was meant to legitimize the multi-city vacation. The real intent was to send Chinese doctors who make very little money in their home country to nice foreign destinations they would otherwise never be able to enjoy. Merit's intent was to induce them to use Merit products in foreign hospitals and to reward them for loyalty. These doctors are decision-makers at Chinese hospitals and "foreign officials" under the FCPA.

158. In another Merit-paid vacation for foreign officials, Merit paid for some 15 Russian physicians to take a tour of the cliffs and sights around Galway, Ireland from June 12-16, 2013. There were two, full sight-seeking days including the Merit-sponsored Galway downtown bus tour and tour to Cliff of Moher on one day and the tour of Connemara & Kylemore Abbey on the next. Merit paid for travel for 20 Russian foreign officials, plus lunches, dinners and alcohol as well as accommodations at the Hotel Raddison Blu.

159. The Merit-sponsored and created itinerary for this loyalty vacation contained numerous photos of the sights in Ireland and corresponding descriptions of the sightseeing schedule. These are just a few:

MERIT MEDICAL

14/06/2013
Bus tour on east and south from Galway

1) **Cliffs Of Moher**
The Cliffs of Moher are is one of Ireland's most visited tourist attractions. Situated in North-West Clare between the villages of Liscannor and Doolin, the Cliffs of Moher are one of Ireland's most spectacular natural wonders. Over 700 feet tall at their highest point, the shale and sandstone cliffs drop almost vertically to the Atlantic

ocean far below. From the top there are views, on a clear day, to the Aran Islands and Galway Bay, the Maum Turk and Twelve Bens mountains in Connemara to the north and Loop Head in Co Clare to the south. The grass roofed Visitor Centre is set into the hillside and offers an all weather experience. The Atlantic Edge Exhibition Area brings to life the story of the Cliffs of Moher. The themed zones of Ocean, Rock, Nature and Man present the setting, geology, wildlife and human stories associated with the cliffs.

2) **The Burren**

The Burren, in County Clare is a barren place, famous for its unique rock formations and exceptional diversity of flora and fauna. There are also large number of historic sites contained within The Burren, making it a popular visitor attraction for the region. Covering an area of approx 300 km2, its boundaries are clearly defined to the north and west by Galway Bay and the Atlantic Ocean, with the villages of Ballyvaughan, Kinvara, Tubber, Corofin, Kilfenora and Lisdoonvarna situated at it's edge. Among the archaeological sites of importance are tombs, burial chambers and the celtic high cross in Kilfenora. The well-preserved Corcomroe Abbey is one of the most popular sights in the area. Many visitors also come for the walking, sea-angling, photography and caving that make this corner of Ireland such an attraction.

160. There is no doubt about the intent of this Merit-sponsored vacation. The itinerary is titled "Merit loyalty program for dealers and customers."

161. While Merit attempted to paper and legitimize the trip as a tour of the Merit manufacturing and R&D facility, there is no real need for physicians to tour a manufacturing facility. In reality, internal emails accurately reveal that the trip was intended to induce the use of Merit products in Russia and to "accelerate our sales":

> As you remember we've planed to send our dealers and phisicians to the Galway for the manufacturing tour. We've discussed it once again with Rishat and came to the decision not to wait until September and organize the tour **12-16 June 2013 in order to accelerate our sales in the 3 and 4 quarter** (as most sales decisions for 2 half year will be held in August).

(Emphasis supplied).

162. These Russian physicians were decision-makers and "foreign officials' under the FCPA.

Misbranding and false, off-label marketing and promotion

QuadraSphere

163. In November, 2006, BioSphere Medical, Inc. ("BioSphere") received 510(k) approval from the FDA to market and distribute QuadraSphere pursuant to 510(k) # K052742. QuadraSphere is governed by 21 CFR 870.3300 as a vascular embolization device and was classified in regulatory class II.

164. 21 CFR 870.3300 states in part:

> § 870.3300 Vascular embolization device.
> (a) ***Identification.*** A vascular embolization device is an intravascular implant intended to control hemorrhaging due to aneurysms, certain types of tumors (e.g., nephroma, hepatoma, uterine fibroids), and arteriovenous malformations. This does not include cyanoacrylates and other embolic agents, which act by polymerization or precipitation. Embolization devices used in neurovascular applications are also not included in this classification, see § 882.5950 of this chapter.

165. The 510(k) describes QuadraSphere as "sterile biocompatible, hydrophilic *(absorbent),* non-resorbable, acrylic copolymer microspheres."

166. The FDA's approval specifically allowed Merit to only "begin marketing [its] device as described in [its] Section 510(k) premarket notification."

167. The QuadraSphere 510(k) discloses the following intended use, "The BioSphere QuadraSphere™ Microspheres are intended for embolization of hypervascularized tumors and peripheral vascular arteriovenous malformations (AVMs)."

168. In 2009, BioSphere submitted to the U.S. FDA an Investigational Device Exemption ("IDE") application for a clinical trial for the use of QuadraSphere to deliver the chemotherapeutic agent doxorubicin for the treatment of primary liver cancer. At the time, and through June 2015, there was no embolic in the United States with FDA market clearance for the treatment of hepatocellular cancer.

169. Per the FDA, an IDE allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification 510(k) submission to FDA.

170. In September, 2010, Merit completed its acquisition of BioSphere and its products, including QuadraSphere.

171. In November 2010, the FDA approved the IDE's proposed protocol for conducting a phase III clinical trial to evaluate the safety and efficacy of QuadraSphere Microspheres in patients with localized, unresectable hepatocellular carcinoma.

172. The trial actually started in 2011, with a stated purpose to "evaluate overall survival in patients treated with HepaSphere/QuadraSphere compared to conventional transarterial chemoembolization with particle PVA" for those patients with hepatocellular carcinoma. This is the first phase III clinical trial for chemoembolization of primary liver cancer in the United States.

173. The trial continues to this day.

174. In March, 2012, a supplemental 510(k) for QuadraSphere was submitted and approved under #K113822. Per this filing, "the only difference between the new subject device and the predicate device is the additional size offering (30 to 60μm) of the QuadraSphere Microsphere. **The indications for use remain the same."** (Bold in original).

175. According to the FDA's 510(k) acceptance and approval letter to Merit, the company was allowed, and only allowed, to "begin marketing your device as described in your Section 510(k) premarket notification."

176. Once a 510(k) has been accepted, if a manufacturer intends to market a Class II device for a new or different indication from that cleared for the predicate device, a new 510(k)

Notification is required to include supporting information to show that the manufacturer has considered what consequences and effects the new use might have on the device's safety and effectiveness.

177. Finally in July 2015, Merit obtained 510(k) clearance for hepatoma for the first time in #K151187. While not specifically referencing "liver cancer," the new clearance has the following indication: "QuadraSphere Microspheres are indicated for embolization of hypervascularized tumors *including hepatorua*, and peripheral arteriovenous malformations." (Emphasis supplied).

178. If #K151187's inclusion of "hepatoma" is meant to refer to liver cancer, then, the very earliest Merit arguably had approval to market QuadraSphere for liver cancer was in July, 2015. However, it consistently and continuously marketed and promoted it for liver cancer in all the time preceding the July, 2015 510(k).

179. Moreover, "hepatoma" is not meant to include metastatic liver cancer. Merit's 2015 10-K filing with the SEC admits that in the U.S., Quadrasphere is not yet indicated for liver cancer:

> We offer Bearing nsPVA® Particles to treat symptomatic uterine fibroids, hypervascularized tumors, and arteriovenous malformations throughout the world. We offer HepaSphere™ Microspheres in Europe, Brazil, and Russia and other emerging markets for drug delivery in the treatment of primary and metastatic liver cancer and QuadraSphere® Microspheres for the treatment of hypervascularized tumor, embolization of hepatoma and arteriovenous malformations in the United States.
> ...
> We are currently conducting a clinical trial in an effort to obtain PMA approval from the FDA to claim the use of the QuadraSphere Microspheres with doxorubicin for the treatment of liver cancer in the United States. ... If we do not obtain FDA approval or clearance of the product use claimed in a clinical trial, we will not be able to promote the subject product for the indicated treatment of the specific disease or condition in the United States.

180. QuadraSphere is technically identical in all respects to Merit's HepaSphere device. HepaSphere has been CE marked (*Conformité Européenne)* in the European Union since 2007 for the embolization of liver cancer and hepatic metastases, with or without delivery of doxorubicin. In other words, the devices are identical except for the indication.

181. In the United States the 510(k) clearance for QuadraSphere (unlike HepaSphere in the E.U.) **does not** include specific indications for the treatment of primary and metastatic liver cancer, nor did it include the indication of colorectal cancer metastasized to the liver. Instead, FDA regulations required formal clinical trials to progress and a new 510(k) prior to seeking to claim the use of QuadraSphere for the treatment of a specific disease or condition, such as primary and metastatic liver cancer, while European Union regulations do not require trials for this class of medical device.

182. Merit's HepaSphere in the E.U. was the only device indicated for liver cancer.

183. Further, Merit markets QuadraSphere for use with doxorubicin. Doxorubicin, however, is not indicated for the treatment of liver cancer (or hepatoma).

184. Instead, per the FDA, doxorubicin is indicated primarily for Adjuvant Breast Cancer ("Doxorubicin hydrochloride injection, USP is indicated as a component of multi-agent adjuvant chemotherapy for treatment of women with auxiliary lymph node involvement following resection of primary breast cancer.") It is also indicated for the following other cancers: acute lymphoblastic leukemia, acute myeloblastic leukemia, Hodgkin lymphoma, non-Hodgkin lymphoma, metastatic breast cancer, metastatic Wilms' tumor, metastatic neuroblastoma, metastatic soft tissue sarcoma, metastatic bone sarcoma, metastatic ovarian carcinoma, metastatic transitional cell bladder carcinoma, metastatic thyroid carcinoma, metastatic gastric carcinoma, and metastatic bronchogenic carcinoma.

185. Merit markets the off-label use of QuadraSphere and for use with doxorubicin, irinotecan and oxaliplatin in all 50 states and sells to all manner of hospitals, including to government buyers like, the VA Medical Centers in Dallas, Phoenix, Boston and the Air Force. Merit internal communications and communications with providers are replete with examples of sales representatives discussing doxorubicin, irinotecan and oxaliplatin loading procedures for use with QuadraSphere with each other and with providers.

186. For example, on December 18, 2014 a Merit sales representative emailed with Dr. Hogg from Northwestern about QuadraSphere and how it is used with doxorubicin to treat liver cancer. He wrote in part:

> We also manufacture Quadrasphere. Which is a lyfolized product that absorbs fluid to reconstitute to a sized sphere.
> Quadraspheres retain a softer consistency which causes nearly complete infarction. They actually mash together forming full contact with vessel walls.
> **Often they are reconstituted with Doxorubicin in liver HCC.**
> **Which product are you interested in?**
> Thanks
> Bucky

(Emphasis supplied).

187. In another example, Merit sales representative, Justin Arnoldi, emailed with Houston Northwest Medical Center about a procedure on a Medicare patient scheduled for Thursday, September 11, 2014 with Dr. Liaw. In the email chain, Merit discusses the doxorubicin dose required for this procedure involving QuadraSphere and sends a doxorubicin loading instruction sheet to the hospital. Included on the chain are the hospital's pharmacy director, pharmacy manager and pharmacy buyer and oncology pharmacist. At no time in the communication does Merit advise that QuadraSphere is off-label for liver cancer and off-label with doxorubicin in this country.

188. Merit also sponsored symposia and booths marketing and promoting the off-label use of QuadraSphere, specifically with doxorubicin. In 2014, Merit attended the Conference on Interventional Oncology in Miami. Merit sponsored a booth and a symposium. Its symposium had 150 attendees and included a discussion by Dr. Ed Kim from Mt. Sinai who delivered data on QuadraSphere with doxorubicin. Merit scanned the identities of all physician attendees and circulated these leads to its salesforce shortly after the conference for personal follow-ups and to induce more use of QuadraSphere off-label.

189. Despite the clear intended use, which does not include liver or colorectal cancer, Merit consistently and continuously marketed QuadraSphere for liver tumors caused by hepatocellular carcinoma and colorectal cancer.

190. Hepatocellular carcinoma is cancer that starts in the liver. It differs from metastatic liver cancer, which originates elsewhere in the body. It is seen more frequently in men than women and is usually seen in people 50 years old or older. Hepatocellular carcinoma is by far the most common type of liver cancer. Doxorubicin is loaded into QuadraSpheres spheres to primarily treat Hepatocellular Carcinoma (HCC).

191. QuadraSphere is also not approved in the United States to treat colorectal cancer that has been metastatic to the liver. Though not on-label, the drug, irinotecan, is primarily loaded into QuadraSpheres to treat colorectal cancer that has been metastatic to the liver.

192. The majority of Merit's false and off-label promotion involving QuadraSphere was to treat cancers in the liver, either primary HCC or colorectal cancer metastasized to the liver, for which it does not have the FDA indications.

193. Moreover, not only has Merit marketed QuadraSphere for indications not contained in its 510(k), but it was marketing for an indication that was and continues to be

studied in a formal clinical trial to determine its safety and effectiveness. Merit knew that no embolic, including QuadraSphere, has been thoroughly studied an approved in this country to treat liver cancer.

194. Nevertheless, Merit had always trained its sales representatives to market QuadraSphere for off-label use. At the Merit national sales meeting on or about September 11, 2014, Merit gave a presentation to the nationwide salesforce in attendance which included how to approach off-label use with physicians.

195. This training included role play by a sales manager to demonstrate how to approach and speak to physicians about off-label uses or QuadraSphere. The manager role played, saying in part, "you know this is off-label, but as long as you are fine talking about it, I am fine continuing" the discussion. This role playing was repeated throughout the day in 4-5 more training sessions. Relator immediately reported this improper training directly to the CEO, who ignored and deflected the compliance concern.

196. Unbeknownst at the time to the Relator, the script used at the national sales meeting was drafted and approved by management including a regional manager, vice president and the global product manager. This script was not and cannot be blamed on a rogue presenter or an off-the-cuff comment. Four times in the script for the national meeting discussion of QuadraSphere, Merit inserted the following bullet point, "*Insert comment about off label discussion.*" The presenters stuck to the written script and trained the entire national salesforce on how to approach and discuss the off-label use of QuadraSphere.

197. Merit was less blatant in written trainings, but achieved the same result. In a written training to all sales representatives titled "QuadraSphere Embolic Training Interventional Division," Merit trains its sales force on the use of QuadraSphere with

doxorubicin to be used to treat liver cancer. The training purposefully interchanges and pairs Hepasphere and QuadraSphere at times, an intentional act done to train the salesforce to always reference Hepasphere's approval and usage in the E.U. and to omit QuadraSphere's lesser (more restrictive) approval status in the U.S.

198. The written training also blatantly discusses the usefulness of QuadraSphere to treat liver cancer. In a training presentation to all salesforce that cover 170 slides, only two slides are the indications discussed. The rest of 168 slides train the sales force on how to market QuadraSphere to treat liver cancer, including which studies to show to physicians, how to load the doxorubicin, and how to address common questions asked by physicians.

199. That presentation is similar to another given to the salesforce titled "Liver" in which out of 60 slides only one discusses the proper indications. The remaining 59 slides discuss how QuadraSphere is uniquely positioned to be the best treatment for liver cancer.

200. Numerous other trainings and presentations are similar, touting QuadraSphere to treat liver cancer in dozens of slides and only mentioning once that is only indicated for hypervascular tumors and AVMs. These presentations do not admit that although the entire training is about QuadraSphere treating liver cancer and for use with doxorubicin, it is not actually approved in the U.S. for these purposes.

201. Merit specifically targets oncologists to market QuadraSphere to their patients. As part of this, Merit gathers the names and contact information from oncologists and posts them on an internal chat room (salesforce.com) so the Merit salesforce can follow up with each of them. One such list is titled "Oncology Leads from Tradeshows" and it provides the name of the oncologist, the name of the Merit sales representative who got credited with the "lead" and the opportunity close date.

202. Carrying out Merit's training, policy and procedures, Merit sales representatives routinely encourage providers to use QuadraSphere off-label. Sales representatives routinely encourage physicians to use QuadraSphere exactly like Hepasphere, and they provide physicians with scientific articles on the off-label use of QuadraSphere.

203. For example, on December 12, 2014, Merit sales representative, Janie Ufberg, emailed Dr. Leschak, an interventional radiologist with the Einstein Helthcare Network, strongly encouraging the physician to switch back to QuadraSphere for off-label use. The email starts:

From: Janie Ufberg
To: leschaks@einstein.edu
Subject: hi!
Date: Friday, December 12, 2014 8:07:00 AM
Attachments: MR10-044-Rev-A-Maleux.pdf
JHC-71602-chemoembolization-with-drug-eluting-microspheres--dem-tace- Sinai.pdf

---

Hi Dr. Leschak, my manager scott told me that he saw you at the AIM meeting in NYC and that you said you were using more eithiodol tace and less Quadrasphere lately.
Please continue to use Quadrasphere and below and attached are 2 significant reasons to do so:

I've attached for you a summary of the Maleaux study that shows Hepasphere versus tace. Outcomes are more favorable with Hepasphere:

(Emphasis supplied).

204. With this email to Dr. Leschak, the sales representative attached two scientific studies on the off-label use of QuadraSphere, and ends the email with "Please let me know your thoughts." Hidden after the body of the email, after the signature block and four more lines down, the following was included at the very bottom of the page "all DEBs are off label in the usa." ("DEBs" is short-hand for drug-eluting beads). This attempted disclaimer does not

and cannot serve to undo the verbal and written off-label marketing and promotion and the intentional confusion of QuadraSphere with Hepasphere to providers.

205. The sales representatives were aware that their marketing of QuadraSphere (sometimes abbreviated as "QS") was off-label and constituted misbranding. On the same day the above email was sent, December 12, 2014, the same sales representative who pushed Dr. Laschak to use QuadraSphere off-label wrote an email to a co-worker acknowledging the misbranding. Mere minutes before sending the email to Dr. Lashak, she wrote in part to another sales-representative:

> You don't think that off label promotion is black and white....? QS not approved for drug loading....
> We are promoting it for deb tace.... we are incentivized to do so.... We are liable and accountable if a dr. tells the fda or if the company wants to fire....

206. At other times, no disclaimer at all was used. Merit was sometimes blatant in its off-label promotion of QuadraSphere. In a 2013 press release, it touted a January 19, 2013 lunch symposium at the Fontainebleau Miami Beach during which it sponsored a CME session on "Advances in Drug-Eluting Embolics for Chemoembolization." In 2013, QuadraSphere had no indication for use with drug-eluting beads.

Merit Laureate® Hydrophilic Guide Wire Demonstration and QuadraSphere® 30-60 µm Microspheres Generate Interest at the 2013 CIO Meeting in Miami

Subscribe

Merit Medical's booth was a frequently visited destination at the 2013 Symposium on Clinical Interventional Oncology (CIO), January 18-19 at the Fontainebleau Hotel in Miami Beach.

The anatomical discovery model allowed attendees to see and feel firsthand the exceptional torque control and turn-by-turn responsiveness of the Merit Laureate Hydrophilic Guide Wire. Attendees also showed a lot of interest in QuadraSphere 30-60 µm Microspheres, Embosphere® Microspheres, Merit Maestro® Microcatheter, H2O Torq™ Torque Device, and the SeaDragon™ Guide Wire Torque Device.

Merit Medical supported a CME Session: **ADVANCES IN DRUG-ELUTING EMBOLICS FOR CHEMOEMBOLIZATION** presented by Dr. Katarina Malagari from the National University of Athens, in Athens, Greece.

Merit Medical had a great show and is looking forward to continuing to provide product innovations and accessories designed to enhance the practice of interventional radiology and oncology.

Patty Jabotte
Marketing Communications Manager

Posted on Thursday, February 28, 2013

+1 Recommend this on Google

207. The next year during the 2014 CIO (Clinical Symposium on Interventional Oncology), again at the Fontainebleau Hotel in Miami Beach, FL, Merit sponsored another symposium on the off-label use of QuadraSphere entitled "Advances in Drug-eluting Embolic for Hepatocellular Carcinoma and Colorectal Metastases." It was held January 18, 2014 and given by Katarina Malagari, MD. Merit promoted the symposium internally and encouraged all its salesforce to send an e-blast of this event to all physicians and target physicians. All of this was done to induce and increase the off-label use of QuadraSphere, including for use with doxorubicin to treat HCC and irinotecan to treat colorectal cancer that has been metastatic to the liver – indications it does not have.

208. Merit engaged in continuous false and off-label marketing of QuadraSphere to physicians and hospitals for use with irinotecan to treat colorectal metastases.

209. For example, sales representatives often provided physicians with articles and studies on the off-label use of QuadraSphere with irinotecan and oxaliplatin, as this email between a sales representative and a physician from September 8, 2014 illustrates:

> **From:** Chad Neb
> **To:** dominic.yee@riaco.com
> **Subject:** FW: Articles for your review
> **Date:** Monday, September 08, 2014 11:16:00 AM
> **Attachments:** Huppert CVIR 2013 HS Irinotecan.pdf
> ATT00001.htm
> Poggi CVIR 2009 Oxali in Cholangiocarcinoma.PDF
> ATT00003.htm
> Poggi HS with oxaliplatin Anti Ca Res 2008.pdf
> ATT00004.htm
>
> Dr. Yee. Thank you for using Quadrasphere last week, and ordering some more in for us. I trust you can find a good place for them in your treatment protocols. I also appreciated you downloading with me after the cases on what you think….as well as introducing me to Brothers BBQ cornbread. I had to do a couple extra miles after that.
> Here are some publications on use of Quads with Irinotecan as well as Oxaliplatin that show effective outcomes using these approaches.
> Thanks again Dr. Yee, let me know when I can help. -chad

210. In another example, a different sales representative promotes QuadraSphere use to a physician for use with "irinotecan and beads." This physician is affiliated with the University of Toledo and the patient in question appears to be named in this email. The sales representative, as is the routine, also offers to assist the hospital's pharmacy with mixing the drug with the beads ("in service"). The sales representative also attaches an article about off-label use.

> **From:** Susan Orr
> **To:** ramon.sevilla@utoledo.edu
> **Subject:** Irinotecan and Beads

Date: Friday, October 24, 2014 7:35:00 AM
Attachments: Huppert HS.IRI.pdf
Hi Ramon,
Here is that article we have on Irinotecan…..if you want something else, I can have our MSL send you some info….
Good to see you and hope to see you somewhere down the road. If you want to use this in Findlay, just give me a little bit of notice to in-service pharmacy.

Embosphere:

211. Per its 510(k), Embosphere Microspheres are spherical microbeads for arterial embolization. They are made of acrylic polymer impregnated with gelatin. They are delivered with the help of a microcatheter in an amount appropriate to the area to be embolized. Six size ranges of EmboSphere were available with the initial 510(k) filing.

212. BioSphere received 510(k) approval for Embosphere Microspheres in 2000 per #K991549 as Product Code HCG and assigned to regulatory class III. The intended use per the 510(k) reads, "EMBOSPHEREE Microspheres are indicated for embolization of hypervascular tumors and arteriovenous malformations."

213. Two years later, in November, 2002, BioSphere filed another 510(k) #K021397. This was for Embosphere Microspheres for UFE under regulation number 21 CFR 882.5950 and was assigned to regulatory class III. The intended use per this 510(k) provides, "Embosphere® and EmboGold™ Microspheres are intended for embolization of arteriovenous malformations and hypervascular tumors, including and uterine fibroids."

214. Effective 2011, Merit disseminated a Hospital Coding Fact Sheet discussing coding and reimbursement rates relating to Embosphere as follows:

Hospital Outpatient Coding

CPT Code	Descriptor	APC	Status Indictor	Payment Level
99213	Established Patient – Level III Office Visit	0605	V	$75.13
72197	MRI, pelvis; without contrast material(s), followed by contrast material(s) and further sequences	0337	S	$533.60
37210*	Uterine fibroid embolization, percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intra-procedural roadmapping, and imaging guidance necessary to complete the procedure	0229	T	$8,025.25
72197	MRI, pelvis; without contrast material(s), followed by contrast material(s) and further sequences	0337	S	$533.60
99213	Established Patient – Level III Office Visit	0605	V	$75.13

**CPT Code 37210 has not been approved for performance in the Ambulatory Surgical Center Setting.*

215. A 2014 internal update noted the change from code 37210 to 37243 for a reimbursement rate of $8,842.66.

216. Merit also published a Physician Coding Fact Sheet for 2011 including the following codes and rates:

CPT Coding

Effective January 1, 2007, the new CPT Code 37210* was added to report embolization of uterine fibroids. The new code is a single all-inclusive code which has been valued to include embolization, selective catheterization, and radiological supervision and interpretation services required for the UFE procedure. **CPT code 37210 should only be billed once per procedure.**

CPT Code	Descriptor	Physician Payment in a Facility - Medicare	Physician Payment in the Office - Medicare
99213	Established Patient – Level III Office Visit	$49.27	$68.97
72197	MRI, pelvis; without contrast material(s), followed by contrast material(s) and further sequences	$112.46	$648.06
37210*	Uterine fibroid embolization, percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intra-procedural roadmapping, and imaging guidance necessary to complete the procedure	$553.14	$3,951.34

217. Embosphere sales topped $86 Million through 2014. These include sales to New Jersey providers including to: Somerset Medical Center, Robert Wood Johnson Univ. Hosp. Somerset, Riverview Medical Center, Trinitas Hospital, Monmouth Medical Center, Atlanticare Regional Medical Center, and others.

218. In March, 2013, Merit announced that it received the CE mark to market in the European Union its line of Embosphere microspheres for embolization of the prostate gland for relief of symptoms related to benign prostatic hyperplasia.

219. No similar approval has been issued in the U.S.

220. At this time, Embosphere is not approved to be used for prostatic artery embolization (PAE) in the United States.

221. Also in 2013, the U.S. FDA approved a Phase I/II Investigational Device Exemption protocol involving Embosphere. This clinical trial aims to determine the safety of prostatic artery embolization for benign prostatic hyperplasia. According to the study, its

primary goal is to document the frequency of side effects, particularly bladder and rectal complications, which may occur as a result of this procedure. Secondarily, the study will provide preliminary data to determine its effectiveness in diminishing obstructive symptoms associated with BPH.

222. This study is underway and has not been completed.

223. Merit falsely markets and promotes Embosphere for two indications that are off-label: (a) prostate; and (b) stomach or bariatric.

224. An example of bariatric kickback and off-label promotion, Merit gave Johns Hopkins and Dr. Clifford Weiss $150,000 to get an IDE to study Embosphere's use in gastric artery embolization for weight loss (an indication Embosphere does not have). Merit funded this in order to ensure good results for the study, to induce the use of its products and devices at Johns Hopkins and so that the researchers would spread the word about Merit's products throughout the industry.

225. Merit's marketing division had a set goal to get "speakers Merit owns" on the podium to promote Merit's products to fellow physicians.

226. At the March 2015 Society of Interventional Radiology (SIR) annual meeting in Atlanta, GA, Merit hosted a "Meet the Author" event on Monday, March 2nd, where Merit selected Dr. Weiss to speak about his off-label study to fellow physicians.

227. Merit's marketing department developed an e-blast which Merit sales representatives sent to physicians in their territories inviting them to the event. The Merit invite lists Dr. Weiss to speak about "emerging applications for embolization."

228. The VP of Sales, Kevin Sterba, posted a photo of the event claiming that over 70 physicians attended. The blow up of the photo clearly shows a slide about the "BEAT" study ("Bariatric Embolization of Arteries for the Treatment of Obesity") from Dr. Weiss.

229. Dr. Weiss' hospital, Johns Hopkins, was paid by Merit for this study, and Dr. Weiss was paid by Merit to give this talk at SIR. Merit also paid for the food and beverage at the event.

230. Those physician attendees were "scanned" by Merit and that attendee list was circulated to Merit salesforce for personal follow-ups with the physic attendees.

231. All of this was meant to induce Dr. Weiss and others to use Embospheres and to do so for off-label indications.

232. Merit also regularly and consistently falsely markets and promotes Embosphere for the off-label PAE indication when it is not so indicated.

233. In 2012, Merit sponsored a PAE Symposium at CIRSE 2012 entitled "Prostate Embolization: Interactive Case Presentation and Discussion." Though held outside the U.S., Merit knew that many U.S. physicians would attend and it strongly encouraged its U.S. salesforce to promote this symposium with all physician contacts with "even the slightest interest in BPH/PAE." Merit scanned the badges of all attendees at the Symposium and circulated the list to its salesforce for personal follow-up after the Symposium, inside the U.S., and with the explicit intent of capturing more physicians and getting them to use Embosphere for the off-label use of PAE.

Endotek

234. Merit inherited and chose not to change, but to continue, the off-label and false promotion and marketing of its predecessor who developed Endotek.

235. Per its 510K (#111611) issued in 2011, the MERIT ENDOTEK EndoMAXX Fully Covered Esophageal Stent is intended for "maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and for occlusion of esophageal fistulae." In other words, it is a Class II device indicated to treat esophageal cancer (malignancy).

236. However, the Endotek stents are promoted and marketed by Merit for use in bariatric surgery for bariatric leaks.

237. Merit paid for a booth and was present marketing Endotek at the November 2014 Obesity Week conference at the Boston Convention Center sponsored by the American Society for Metabolic and Bariatric Surgery (ASMBS) and The Obesity Society (TOS). Its print profile stated "Merit Medical Endotek integrates inflation devices, guide wires, and other accessories with next-generation stent technology, giving you the advanced tools you need to achieve better patient outcomes."

238. No part of the Obesity Week conference covered esophageal cancer. Therefore, the only purpose of Merit's promotion of Endotek was for the false and off-label promotion of Endotek for bariatric surgery.

239. The Endotek division was acquired years ago by Merit, and its predecessor had its own issues with off-label marketing prior to Merit's acquisition. The president of this division, Darla Gill, (one of the founders of Merit) once told Relator that at least 50% of Endotek's total revenue is the result of off-label use, a statistic Merit exploits in its marketing and promotion.

240. In addition to the promotion, Merit also pays its sales representatives and covers their costs (in expense reports) to travel to work on bariatric/off-label cases. For example, it

covered a $975.10 flight charge for sales employee Brandon Markle to cover a bariatric case for S.D. Merit kept track of these expenses.

CO2 Kits

241. Lastly, Merit also engages in the false and off-label promotion and marketing of its CO2 kits. CO2 is used as a replacement for contrast for patients who cannot tolerate normal contrast.

242. Merit had a CO2 kit packaged together and it asked the FDA what it would take to get the indication for use in patients who cannot tolerate contrast. The FDA responded that it would be very difficult to achieve and a very onerous a process.

243. After this discussion with the FDA, Merit decided to not attempt to obtain the indication and, instead, to discontinue it as a packaged kit.

244. However, Merit did not disclose to the FDA or otherwise note anywhere that it continues to sell the exact components of the kit as 3 separate items that get purchased together at Merit's encouragement and facilitation.

245. In other words, after inquiring with the FDA and deciding it would be too complicated or difficult to get the indication, Merit simply started selling the exact same items, just de-packaged so as to avoid FDA detection and avoid the delay and cost associated with getting the required indication.

246. Merit's LAP funds have also been used to sponsor events marketing and inducing the use of its CO2 units despite the lack of indication from the FDA. On December 19, 2014, a Merit sales representative emailed management about the following CO2 event:

> Kevin/Jim
> Dr. Caridi called me on Wednesday afternoon looking for help to support a cocktail reception at an upcoming program he is having on CO2 at Tulane. He

> is under the impression that we are supporting the meeting, but this is the first I have heard of it. There will apparently be a cocktail reception for those attending on the afternoon of the conference and he is soliciting support to fund the reception from four companies at $500.00 each.
> At the present time this is all the information that I have received but apparently the CME department will be contacting me with more details which I will forward when received. I wanted to forward this to you guys at this time to give you a heads up.
> I have replied to Dr. Caridi that I would pass this along to you guys and also requested that he use his influence to move the process at Tulane of getting Quads and Maestro in when he returns after Christmas. The last conversation we had was that it was in the committee.
> Thanks
> Tim

247. The use of LAP funds was approved for this.

248. In other instances, Merit sales representatives promote their CO2 kits to physicians but are generally careful to order them separately and then teach the physician how to connect them. Merit sales representatives know that this conduct is off-label and have admitted it in internal emails:

> **From:** James Williams R.T. (R)
> **Sent:** Tuesday, November 18, 2014 9:34 AM
> **To:** Jesse Lindsey
> **Subject:** FW: Potential Products That Hypothetically Could Be Used For C02 Procedures
>
> Here is the gator kits for what you are looking for. I looked at your docs drawings and we could possible do that but it's a custom kit. If you can try and work with this kit as you wont get asked any questions and as soon as you create that other kit someone may ask what its for and start digging as **this is all off label use**. I would suggest ordering in a couple of each of these kits and showing the doc. We can facetime at some point and I can show you how they connect. Let me know.

(Emphasis supplied).

249. In another example, in March, 2014, Merit emailed with Nassau University Medical Center about the CO2 kits. The hospital states that it has "obtained all the Merit

products for CO2 dispensing for future TIPS procedures" and then asks Merit to come into the hospital to provide training on how to do the setup. Merit obliges and sets up the training.

250. In none of these emails does Merit advise that the CO2 kits are off-label as they are promoting them and setting them up for the providers.

COUNT 1
FALSE CLAIMS ACT
(Violation of 31 U.S.C. § 3729(a)(1)(A))

251. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

252. This is a claim brought by Relator and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. § 3730 for Defendant Merit's violations of 31 U.S.C. § 3729 *et seq.*

253. The Federal False Claims Act, 31U.S.C.§ 3729(a)(l)(A), provides:

> Liability for certain acts. Any person who--
> (A) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval ....

Id.

254. By virtue of the above-described acts, among others, since at least 2009, Defendant Merit knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval, and upon information and belief, continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the United States, in violation of 31 U.S.C. § 3729(a)(l)(A).

255. In addition, the AKS, 42 U.S.C. § 1320a-7b(b)(2)(B), prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or

services for which payment may be made in whole or in part under any public assistance program. Compliance with the AKS is an express condition of eligibility and payment of a claims submission for reimbursement under Medicare.

256. By engaging in the fraudulent and illegal practices and conduct alleged herein, including but limited to the *quid pro quo* payments, trips, advertising, among other things, Merit violated the AKS.

257. Merit's material violations of the AKS led to the presentation to Medicare and its agents' claims for patients unlawfully referred by physicians who were offered and who accepted kickbacks and then presented those claims to Medicare and other government payers.

258. Merit also caused the submission of false claims for off-label use of its products, including QuadraSphere, Embosphere, CO2 kits and Endotek, as detailed above.

259. Merit intended for all of these claims to be paid by the Federal Government health care programs and other government payers.

260. Each of the claims that Merit caused to be submitted for each procedure done on each patient is a separate, false and fraudulent claim.

261. Merit caused these claims to be presented with actual knowledge of their falsity, or in deliberate ignorance or reckless disregard that such claims were false for medical devices and uses that were not approved, were off-label, were misbranded and were the results of illegal kickbacks.

262. For those claims that Merit submitted or caused to be submitted, it was foreseeable, and in fact the intended result, that those claims would be submitted. Further, at all times relevant to this herein, Merit acted with the requisite scienter.

263. Such conduct constitutes a violation of the False Claims Act, 31 U.S.C.

§ 3729(a)(I).

264. The United States was unaware of the fraud and fraudulent schemes detailed herein and but for this disclosure, would not have discovered it and its true breadth and scope.

265. The amounts of the false or fraudulent claims to the United States was material. These claims should not have been paid at all by Federal or state health care insurers, or in the alternative, payments should have been limited since the medical devices were being used off-label at the manufacturer's false and misleading promotion, suggestion, training and instruction, and further, since the claims submitted were the results of, and were each tainted by, an intentional kickback scheme.

266. As a result of these false or fraudulent claims submitted or caused to be submitted by Merit, the United States Treasury, through Medicare, Medicaid and other federal health care programs' payments of these claims, has suffered damage in an amount to be determined at trial, believed to exceed tens of millions of dollars, plus a civil penalty of $5,500 to $11,000 for each such false claim presented or caused to be presented by Defendants.

COUNT 2
FALSE CLAIMS ACT
(Violation of 31 U.S.C. § 3729(a)(1)(B))

267. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

268. This is a claim brought by Relator and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. § 3730 for Defendant's violations of 31 U.S.C. § 3729 *et seq.*

269. The Federal False Claims Act, 31 U.S.C. § 3729(a)(l)(B) provides:

> Liability for certain acts. Any person who--
> (B) knowingly makes, uses, or causes to be made or used, a false record or

statement material to a false or fraudulent claim ...

270. For purposes of obtaining reimbursement or aiding and assisting to obtain payment or approval of Medicare, Medicaid, or other federal health care programs, Merit made or presented or caused to be made or presented false or fraudulent records to the United States, knowing these records to be false or fraudulent or acting with reckless disregard or deliberate ignorance thereof, and it continues to do so, all in violation of 31 U.S.C. § 3729(a)(1)(B).

271. Also, by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented misleading and false or fraudulent claims for payment or approval to the Federally funded Medicare Program and other federal and state health care programs and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

272. The claims Defendant submitted or caused to be submitted failed to disclose the underlying violation of the AKS and/or affirmatively misrepresented that the clams were made in compliance with all applicable laws, including the AKS.

273. For those records and/or statements that Defendants made or used or caused to be made or used, it was foreseeable and in fact the intended result that those statements and/or records would result in the payment of false reimbursement claims.

274. Further, at all times relevant hereto, Defendants acted with the requisite scienter.

275. Such conduct constitutes a violation of the False Claims Act, 31 U.S.C. § 3729(a)(2).

276. The United States was unaware of the fraud and fraudulent schemes detailed herein and but for this disclosure, would not have discovered it and its true breadth and scope.

277. In reliance on the false and fraudulent records presented or caused to be presented by Merit, the United States authorized payments to be made which greatly enriched Merit and which damaged the United States Government.

278. These claims should not have been paid at all by Federal or state health care insurers, or in the alternative, payments should have been limited since the medical devices were being used off-label at the manufacturer's false and misleading promotion, suggestion, training and instruction, and further, since these claims were the results of, and were tainted by, an intentional kickback scheme.

279. As a result of these false or fraudulent claims submitted or caused to be submitted by Merit, the United States paid the claims, resulting in damages to the United States, in an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false record and/or statement made or used or caused to be made or used by Defendant.

COUNT 3
False Claim Act
(31 U.S.C. § 3729(a)(1)(C))

280. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

281. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, prohibits any person from knowingly and willfully offering or paying any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to any person to induce such person to purchase, order, arrange for, or recommend purchasing or ordering any good,

service, or item for which payment may be made (in whole or in part) under a federal health care program.

282. Merit has knowingly and willfully offered and paid remuneration directly to physicians to induce those physicians to purchase, order, or arrange for the purchasing or ordering of Merit equipment, devices and products, including but not limited to: QuadraSphere, Embosphere, CO2 kits, Endotek, Maestro, guide wires and other Merit products, where payment would be made (in whole or in part) under a Federal health care program.

283. Merit knew that each Medicare and Medicaid provider is required to enter into a provider agreement with the Government (CMS Form 855A, 855B, or 8551) and that under the terms of those agreements, each Medicare or Medicaid provider certifies that it will comply with all laws and regulations concerning proper practices for those providers. One of the laws included in this certification is the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(B).

284. A Medicare or Medicaid provider's compliance with the provider agreement is a condition of participation and a condition of payment under the Medicare and Medicaid programs.

285. Physicians who receive payments in violation of the Anti-Kickback Statute violate their certifications and are disqualified from receiving payment as part of the Medicare and/or Medicaid programs.

286. As a result of Merit's offers and payments to physicians in violation of the Anti-Kickback Statute, and the physicians' acceptance and receipt of those payments, the physicians became ineligible to receive payment under the Medicare and Medicaid programs.

287. It was foreseeable, and indeed intended, and Merit knew and intended that providers who were ineligible under the Medicare and Medicaid programs would submit

claims for payment to the Medicare and Medicaid programs for the purchase and use of Merit equipment, devices and products. These claims by physicians were false, and Merit caused their submission.

288. As set forth in the preceding paragraphs, Merit conspired with private physicians, other health care providers and other third-party interests who assisted Defendant in its illegal kickback schemes to defraud the United States by getting false and/or fraudulent Medicare and Medicaid claims paid in violation of 31 U.S.C. § 3729(a)(1)(C).

289. Merit, by and through its officers, agents and employees, authorized and encouraged its various officer agents and employees to take the actions set forth herein.

290. The United States was unaware of the fraud and fraudulent schemes detailed herein, and but for this disclosure, would not have discovered it and its true breadth and scope.

291. In reliance on the false and fraudulent records presented or caused to be presented by Merit, the United States authorized payments to be made which greatly enriched Merit and which damaged the United States Government.

292. These claims should not have been paid at all by Federal or state health care insurers, or in the alternative, payments should have been limited since the medical devices were being used off-label at the manufacturer's false and misleading suggestion, training and instruction, and further, since these claims were the results of, and were tainted by, an intentional kickback scheme.

293. As a result of these false or fraudulent claims submitted or caused to be submitted by Merit, the United States paid the claims, resulting in damages to the United States, in an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false record and/or statement made or used or caused to be made or used by Defendant.

COUNT 4
Violations of the Federal False Claims Act, 31 U.S.C. § 3729(a)(l)(G)

294. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

295. This is a claim brought by Relator and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. § 3730, for Defendant Merit's violations of 31U.S.C. § 3729 *et seq.*

296. The Federal False Claims Act, 31 U.S.C. § 3729(a)(l)(G), provides:

> Liability for certain acts. Any person who--
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government ...

Id. The term "obligation" means:

> an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, form a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment ...

31 U.S.C. § 3729(b)(3).

297. By virtue of the above-described acts, among others, Defendant Merit knowingly made, used, or caused to be made or used false records or statements, and possibly continues to do so, in violation of 31U.S.C. § 3729(a)(l)(G).

298. Relator, and others, informed Defendant of the various compliance problems alleged herein, including to the CEO and, at times, the Board of Directors as well, but Merit never took the required and appropriate steps to cease the fraudulent conduct, satisfy the obligation owed to the United States, refund or return such overpayments, and to inform

Medicare of the overbilling, and it instead continued to retain the same without proper notice and reimbursement to the Government as of at least October 2015 when Relator quit his employment. It is unclear whether Merit is compliant with its regulatory obligations at the present time since Relator is not presently at the company.

299. As a result of Defendant's violations of 31 U.S.C. § 3729 (a)(l)(G), the United States has suffered substantial losses in an amount that exceeds tens of millions of dollars, and therefore is entitled to treble damages under the False Claims Act, in an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each claim.

PRAYER FOR RELIEF

WHEREFORE, Relator prays, on behalf of the United States and himself, that on final trial of this case, judgment be entered in favor the United States and against Defendant as follows:

A. On the First Cause of Action under the False Claims Act, for the amount of the United States' damages, multiplied as required by law and for such civil penalties as are allowed by law, including, but not limited to, statutory penalties for each violation, attorney's fees and costs;

B. On the Second Cause of Action under the False Claims Act, for the amount of the United States' damages, multiplied as required by law and for such civil penalties as are allowed by law, including, but not limited to, statutory penalties for each violation, attorney's fees and costs;

C. On the Third Cause of Action under the False Claims Act, for the amount of the United States' damages, multiplied as required by law and for such civil penalties as are

allowed by law, including, but not limited to, statutory penalties for each violation, attorney's fees and costs;

D. On the Fourth Cause of Action under the False Claims Act, for the amount of the United States' damages, multiplied as required by law and for such civil penalties as are allowed by law, including, but not limited to, statutory penalties for each violation, attorney's fees and costs;

E. For the costs of this action, prejudgment interest, interest on the judgment, attorney's fees and for any other and further relief to which Plaintiff, the United States and Relator may be justly entitled.

F. That Relator be awarded the maximum amount allowed as a Relator's Share pursuant to §3730(d) of the federal False Claims Act; and

G. That Relator recover such other relief as the Court deems just and proper, or that is necessary to make Relator whole.

COUNT 5
ILLINOIS WHISTLEBLOWER REWARD & PROTECTION ACT

300. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

301. This is a *qui tam* action brought by Relator on behalf of the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq.*

302. 740 ILCS 175/3(a) provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used,

a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

303. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

304. The off-label marketing and promotion, misbranding and the kickback schemes detailed in this Complaint occur nationwide. This conduct and these practices occur in every state in the country by Merit personnel, including in Illinois. Defendant violated 305 ILCS 5/8A-3(b) by engaging in the kickback scheme and related conduct described in this Complaint.

305. Defendant furthermore violated 740 ILCS 175/3(a)(1), (2), (3) by: (1) knowingly causing hundreds of thousands of false claims to be made, used and presented to the State of Illinois; (2) causing false records or statements to get a false or fraudulent claim paid or approved by the State; and (3) conspiring to defraud the State by getting a false or fraudulent claim allowed or paid. It is also liable by virtue of its systematic violation of Federal and state laws, including the FDCA, FCPA, Federal Anti-Kickback Act, and the Illinois Vendor Fraud and Kickback statute.

306. The State of Illinois, by and through the Illinois Medicaid program and other state healthcare programs, paid the claims submitted by healthcare providers and third party payers in connection therewith -- an outcome which was intended by the Defendant.

307. The State was unaware of this fraud, and could not have uncovered the Defendant's scheme absent this disclosure by the Relator.

308. Compliance with applicable Medicare, Medicaid and the various other Federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Illinois in connection with Defendant's conduct. Compliance with applicable Illinois statutes, regulations and manuals was also an express condition of payment of claims submitted to the State of Illinois.

309. Additionally, Illinois specifically requires all Medicaid Providers to agree, "on a continuing basis, to comply with federal standards specified in Title XIX and XXI of the Social Security Act and with all other applicable federal and state laws and regulations." (Agreement For Participation Illinois Medical Assistance Program). These requirements are more than just conditions of participation, upon information and belief, they are conditions of payment.

310. The claims submitted by Illinois providers in connection with Defendant's equipment, devices and products violated Federal and state laws as well as the Illinois provider agreements and should not have been paid.

311. Had the State of Illinois known that Defendant was violating the Federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims caused to be submitted by Defendant through healthcare providers and third party payers in connection with that conduct.

312. As a result of Defendant's violations of 740 ILCS 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

313. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on behalf of himself and the State of Illinois.

314. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the Federal claim and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To Relator:

(1) The maximum amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) That Relator be awarded the maximum amount allowed as a Relator's Share under State law;

(4) An award of reasonable attorneys' fees and costs; and

(5) Such further relief as this Court deems equitable and just.

To the State Of Illinois:

(1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Illinois;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

COUNT 6
CALIFORNIA FALSE CLAIMS ACT

315. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

316. This is a *qui tam* action brought by Relator on behalf of the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 *et seq.*

317. Cal. Gov't Code § 12651(a) provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof; a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
> (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.
> (4) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

318. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code § 650 and 650.1 and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.

319. The misleading and false off-label marketing and promotion, misbranding and the kickback schemes detailed in this Complaint are nationwide. This conduct and these practices occur in every state in the country by Merit personnel, including in California. Defendant violated Cal. Bus. & Prof. Code § 650 and 650.1 and Cal. Welf. & Inst. Code § 14107.2 by engaging in the kickback scheme and related conduct described in this Complaint.

320. Defendant furthermore violated Cal. Gov't Code § 12651(a)(1),(2),(3),(4)) by: (1) knowingly causing hundreds of thousands of false claims to be made, used and presented to the State of California; (2) causing false records or statements to get a false or fraudulent claim paid or approved by the State; (3) conspiring to defraud the State by getting a false or fraudulent claim allowed or paid; (4) discovering and knowing about the falsity of these claims but, failing to disclose, and not notifying the State and returning the payments. It is also liable by virtue of its systematic violation of Federal and state laws, including the FDCA, FCPA, Federal Anti-Kickback Act, and Cal. Bus. & Prof. Code § 650-650.1 and Cal. Welf. & Inst. Code § 14107.2 and by virtue of the fact that none of the claims submitted in connection with its conduct were eligible for reimbursement by the Government-funded healthcare programs.

321. The State of California, by and through the California Medicaid program and other State healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith -- an outcome which was intended by the Defendant.

322. The State was unaware of this fraud, and could not have uncovered the Defendant's scheme absent this disclosure by the Relator.

323. Compliance with applicable Medicare, Medi-Cal and the various other Federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of California in connection with Defendant's conduct. Compliance with applicable California statutes, regulations and manuals was also an express condition of payment of claims submitted to the State of California.

324. Additionally, in order to be eligible to participate as a Medi-Cal provider, California requires all Providers to agree that they:

> shall not solicit, request, accept, or receive, any rebate, refund, commission, preference, patronage, dividend, discount, or any other gratuitous consideration, in connection with the rendering of health care services to any Medi-Cal beneficiary. Provider further agrees that it will not take any other action or receive any other benefit prohibited by state or federal law.

(Medi-Cal Provider Agreement). These requirements are more than just conditions of participation; upon information and belief, they are conditions of payment. The claims submitted by California providers in connection with Defendant's equipment, devices and products violated Federal and state laws as well as the California provider agreements and should not have been paid.

325. Had the State of California known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims caused to be submitted by Defendant through healthcare providers and third party payers in connection with that conduct.

326. As a result of Defendant's violations of Cal. Gov't Code § 12651 (a), California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

327. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of himself and the State of California.

328. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following

damages to the following parties and against Defendant:

To the State Of California:

(1) Three times the amount of actual damages which the State of California has sustained as a result of Defendant's conduct;

(2) A civil penalty of up to $10,000 for each false claim which Defendant presented or caused to be presented to the State of California;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) That Relator be awarded the maximum amount allowed as a Relator's Share under State law;

(4) An award of reasonable attorneys' fees and costs; and

(5) Such further relief as this Court deems equitable and just.

COUNT 7
FLORIDA FALSE CLAIMS ACT

329. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

330. This is a *qui tam* action brought by Relator on behalf of the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

331. Fla. Stat. § 68.082(2) provides liability for any person who:

> (a) knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;
> (c) conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed-or paid.

332. In addition, Fla. Stat. § 409.920 makes it a crime to:

> (c) knowingly charge, solicit, accept, or receive anything of value, other than an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency or its fiscal agent for any payment received from a third-party source;
> ***
> (e) knowingly, solicit, offer, payor receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering; or arranging, for or recommending, obtaining, purchasing, leasing, or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

333. Fla. Stat. §456.054(2) also prohibits the offering, payment, solicitation, or receipt of a kickback to a healthcare provider, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for referring or soliciting patients.

334. The false and misleading off-label marketing and promotion, misbranding and the unlawful kickback schemes detailed in this Complaint are nationwide. This conduct and these practices occur in every state in the country by Merit employees and agents, including in Florida. Defendant violated Fla. Stat. § 409.920(c) and (e) and §456.054(2) by engaging in the kickback scheme and related conduct described in this Complaint.

335. Defendant furthermore violated Fla. Stat. § 68.082(2)(a),(b),(c) by: (1) knowingly causing hundreds of thousands of false claims to be made, used and presented to the State; (2) causing false records or statements to get a false or fraudulent claim paid or approved

by the State; and (3) conspiring to defraud the State by getting a false or fraudulent claim allowed or paid. It is also liable by virtue of its systematic violation of Federal and state laws, including the FDCA, FCPA, Federal Anti-Kickback Act, and Fla. Stat. § 409.920(c) and (e) and §456.054(2) and by virtue of the fact that none of the claims submitted in connection with its conduct were eligible for reimbursement by the government-funded healthcare programs.

336. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, paid the claims submitted by healthcare providers and third party payers in connection therewith -- an outcome which was intended by the Defendant.

337. The State was unaware of this fraud, and could not have uncovered the Defendant's scheme absent this disclosure by the Relator.

338. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Defendant's conduct. Eligibility to act as a provider was contingent upon compliance with applicable Florida statutes, regulations and manuals. By not complying, the providers become ineligible to participate and ineligible to receive Medicaid reimbursement. The claims submitted by Florida providers in connection with Defendant's equipment, devices and products violated Federal and state laws as well as the Florida provider agreements and should not have been paid.

339. Had the State of Florida known that Defendant was violating the Federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims

caused to be submitted by Defendant through healthcare providers and third party payers in connection with that conduct.

340. As a result of Defendant's violations of Fla. Stat. §68.082(2), the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

341. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of himself and the State of Florida.

342. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the Federal claim and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State Of Florida:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Florida;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To the Relator:

(1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) That Relator be awarded the maximum amount allowed as a Relator's Share under State law;

(4) An award of reasonable attorneys' fees and costs; and

(5) Such further relief as this Court deems equitable and just.

COUNT 8
TEXAS FALSE CLAIMS ACT

343. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

344. This is a *qui tam* action brought by Relator on behalf of the State of Texas to recover double damages and civil penalties under Tex. Hum. Res. Code Ann. §§ 36.001 *et. seq.*

345. Tex. Hum. Res. Code Ann. § 36.002 provides that "a person commits an unlawful act if the person":

> (1) knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;
>
> (2) knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;
>
> (3) knowingly applies for and receives a benefit or payment on behalf of another person under the Medicaid program and converts any part of the benefit or payment to a use other than for the benefit of the person on whose behalf it was received;
>
> (4) knowingly makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:
>
> (A) the conditions or operation of a facility in order that the facility may qualify for certification or recertification required by the Medicaid program, including certification or recertification as:
>
> (i) a hospital;

(ii) a nursing facility or skilled nursing facility;
(iii) a hospice;
(iv) an intermediate care facility for the mentally retarded;
(v) an assisted living facility; or
(vi) a home health agency; or

(B) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

(5) except as authorized under the Medicaid program, knowingly pays, charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program;

(6) knowingly presents or causes to be presented a claim for payment under the Medicaid program for a product provided or a service rendered by a person who:

(A) is not licensed to provide the product or render the service, if a license is required; or

(B) is not licensed in the manner claimed;

(7) knowingly makes or causes to be made a claim under the Medicaid program for:

(A) a service or product that has not been approved or acquiesced in by a treating physician or health care practitioner;

(B) a service or product that is substantially inadequate or inappropriate when compared to generally recognized standards within the particular discipline or within the health care industry; or

(C) a product that has been adulterated, debased, mislabeled, or that is otherwise inappropriate;

(8) makes a claim under the Medicaid program and knowingly fails to indicate the type of license and the identification number of the licensed health care provider who actually provided the service;

(9) knowingly enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program or a fiscal agent;

(10) is a managed care organization that contracts with the Health and Human Services Commission or other state agency to provide or arrange to provide health care benefits or services to individuals eligible under the Medicaid program and knowingly:

(A) fails to provide to an individual a health care benefit or service that the organization is required to provide under the contract;

(B) fails to provide to the commission or appropriate state agency information required to be provided by law, commission or agency rule, or contractual provision; or

(C) engages in a fraudulent activity in connection with the enrollment of an individual eligible under the Medicaid program in the organization's managed care plan or in connection with marketing the organization's services to an individual eligible under the Medicaid program;

(11) knowingly obstructs an investigation by the attorney general of an alleged unlawful act under this section;

(12) knowingly makes, uses, or causes the making or use of a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to this state under the Medicaid program; or

(13) knowingly engages in conduct that constitutes a violation under Section 32.039(b).

346. The false and misleading off-label marketing and promotion, misbranding and the kickback schemes detailed in this Complaint are nationwide. This conduct and these practices occur in every state in the country by Merit personnel, including in Texas. Defendant violated Tex. Hum. Res. Code § 36.002, including subsections (1),(2), (3), (5), (7), & (9), (10), & (12), and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Texas by its deliberate and systematic violation of Federal and state laws, including the FDCA, Federal Anti-kickback Act and § 36.002, and by virtue of the fact that none of the claims submitted in connection with its conduct were eligible for reimbursement by the government-funded healthcare programs.

347. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith -- an outcome which was intended by the Defendant.

348. The State was unaware of this fraud, and could not have uncovered the Defendant's scheme absent this disclosure by the Relator.

349. Compliance with applicable Medicare, Medicaid, various other Federal and state laws cited herein, applicable Texas statutes, regulations and reimbursement manuals was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Defendant's conduct. By not complying with these, the providers become ineligible to participate and ineligible to receive Medicaid reimbursement. Additionally, to be eligible to act as a provider and receive reimbursement, Texas requires all Medicaid Providers to agree that their provider agreement "is subject to all state and federal laws and regulations relating to fraud, abuse and waste in health care and the Medicaid program." (HHSC Medicaid Provider Agreement). The claims submitted by Texas providers in connection with Defendant's equipment, devices and products violated Federal and state laws as well as the Texas provider agreements and should not have been paid.

350. Had the State of Texas known that Defendant was violating the Federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false, misleading or omitted material information, it would not have paid the claims caused to be submitted by Defendant through healthcare providers and third party payers in connection with that conduct.

351. As a result of Defendant's violations of § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

352. Defendant did not, within 30 days after it first obtained information as to such violations, furnish such information to officials of the state responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and has not otherwise furnished information to the state regarding the claims for reimbursement at issue.

353. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to § 36.101 on behalf of himself and the State of Texas.

354. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State Of Texas:

(1) Two times the amount of actual damages which the State of Texas has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $10,000 pursuant to Tex. Hum. Res. Code § 36.025 for each false claim which Defendant cause to be presented to the state of Texas;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Tex. Hum. Res. Code Ann. §§ 36.001 *et. seq* and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) That Relator be awarded the maximum amount allowed as a Relator's Share under State law;

(4) An award of reasonable attorneys; fees and costs; and

(5) Such further relief as this Court deems equitable and just.

COUNT 9
MASSACHUSETTS FALSE CLAIMS ACT

355. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

356. ALM GL ch. 12, § 5B provides liability, in part, for:

(a) Any person who:
(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses or causes to be made or used a false record or statement material to a false or fraudulent claim;

(3) conspires to commit a violation of this subsection;

(4) knowingly presents, or causes to be presented, a claim that includes items or services resulting from a violation of section 1128B of the Social Security Act, 42 U.S.C. 1320a-7b, or section 41 of chapter 118E;

...
(9) knowingly makes, uses or causes to be made or used a false record or statement material to an obligation to pay or to transmit money or property to the commonwealth or a political subdivision thereof, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the commonwealth or a political subdivision thereof; or

(10) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or a political subdivision thereof, or is a beneficiary of an overpayment from the commonwealth or a political subdivision thereof, and who subsequently discovers the falsity of the claim or the receipt of overpayment and fails to disclose the false claim or receipt of overpayment to the commonwealth or a political subdivision by the later of:

(i) the date which is 60 days after the date on which the false claim or receipt of overpayment was identified; or

(ii) the date any corresponding cost report is due, if applicable, shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,500 and not more than $11,000 per violation, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. No. 101-410 section 5, 104 Stat. 891, note following 28 U.S.C. section 2461, plus 3 times the amount of damages, including consequential damages, that the commonwealth or a political subdivision thereof sustains because of such violation. A person violating sections 5B to 5O, inclusive, shall also be liable to the commonwealth or a political subdivision thereof for the expenses of the civil action brought to recover any such penalty or damages including, without limitation, reasonable attorneys' fees, reasonable expert fees and the costs of investigation, as set forth below. Costs recoverable under said sections 5B to 5O, inclusive, shall also include the costs of any review or investigation undertaken by the attorney general, or by the state auditor or the inspector general in cooperation with the attorney general.

357. In addition, ALM GL ch. 118E, § 41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid program.

358. The false and misleading off-label marketing and promotion, misbranding and the kickback schemes detailed in this Complaint are nationwide. This conduct and these practices occur in every state in the country by Merit personnel, including in Massachusetts. Defendant violated Chap. 118E § 41 by engaging in the kickback scheme and related conduct described in this Complaint.

359. Defendant further violated ALM GL ch. 12, § 5B by: (1) conspiring to commit fraud; (2) knowingly causing hundreds of thousands of false claims to be made, used and

presented to the Commonwealth of Massachusetts; (3) concealment and failure to report overpayment; (4) its deliberate and systematic violation of Federal and state laws, including the FDCA, Federal Anti-Kickback Act, ALM GL ch. 118E, § 41; and (5) by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

360. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith -- an outcome which was intended by the Defendant.

361. The State was unaware of this fraud, and could not have uncovered the Defendant's scheme absent this disclosure by the Relator.

362. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Massachusetts in connection with Defendant's conduct. To be eligible to receive reimbursement from the Commonwealth, compliance with applicable Massachusetts statutes, regulations and reimbursement manuals is mandatory. The claims submitted by Massachusetts providers in connection with Defendant's equipment, devices and products violated Federal and state laws as well as the Massachusetts provider agreements and should not have been paid.

363. Had the Commonwealth of Massachusetts known that Defendant was violating the Federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not

have paid the claims caused to be submitted by Defendant through by healthcare providers and third party payers in connection with that conduct.

364. As a result of Defendant's violations of Massachusetts laws cited herein, the Commonwealth of Massachusetts has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

365. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to ALM GL ch. 12, § 5 *et. seq.* on behalf of himself and the Commonwealth of Massachusetts.

366. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claims, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Realtor respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the Commonwealth of Massachusetts:

(1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the Commonwealth of Massachusetts;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action..

To Relator:

(1) The maximum amount allowed pursuant to ALM GL ch. 12, § 5F and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relators incurred in connection with this action;

(3) That Relator be awarded the maximum amount allowed as a Relator's Share under State law;

(4) An award of reasonable attorneys' fees and costs; and

(5) Such further relief as this Court deems equitable and just.

COUNT 10
TENNESSEE FALSE CLAIMS ACT

367. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

368. This is a *qui tam* action brought by Relator on behalf of the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

369. § 71-5-182(a)(1) provides liability in part for any person who:

(1) (A) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval under the Medicaid program;

(B) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim to get a false or fraudulent claim under the Medicaid program paid for or approved;

(C) Conspires to commit a violation of subdivision (a)(1)(A), (a)(1)((B), or (a)(1)((D); or

(D) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money, or property to the state, or knowingly conceals, or knowingly and improperly, avoids, or decreases an obligation to pay or transmit money or property to the state, relative to the Medicaid program;

The off-label marketing and promotion, misbranding and the kickback schemes detailed above are nationwide. This conduct and these practices occur in every State in the country by Merit personnel, including in Tennessee. Defendant violated Tenn. Code Ann. § 71-5-182(a)(1) (1) knowingly causing hundreds of thousands of false claims to be made, used and presented to the

State; (2) causing false records or statements to get a false or fraudulent claim paid or approved by the State; (3) conspiring to defraud the State by getting a false or fraudulent claim allowed or paid; and (4) concealment and non-disclosure of the overpayments and fraud. It is also liable by virtue of its systematic violation of Federal and state laws, including the FDCA, FCPA, Federal Anti-Kickback Act, and the Tennessee Medicaid False Claims Act.

370. The State of Tennessee, by and through the Tennessee Medicaid program and other state healthcare programs, paid the claims submitted by healthcare providers and third party payers in connection therewith -- an outcome which was intended by the Defendant.

371. The State was unaware of this fraud, and could not have uncovered the Defendant's scheme absent this disclosure by the Relator.

372. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Defendant's conduct. To be eligible to receive reimbursement as a provider, compliance with applicable Tennessee statutes, regulations, reimbursement manuals and provider agreement is mandatory. The claims submitted by Tennessee providers in connection with Defendant's equipment, devices and products violated Federal and state laws as well as the Tennessee provider agreements and should not have been paid.

373. Had the State of Tennessee known that Defendant was violating the Federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs and/or were premised on false, omitted and/or misleading information, it would not have paid the

claims caused to be submitted by Defendant through by healthcare providers and third party payers in connection with that conduct.

374. As a result of Defendant's violations of Tenn. Code Ann. § 71-5-181 *et seq.*, the State of Tennessee has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

375. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of himself and the State of Tennessee.

376. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claims and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Tennessee:

(1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Tennessee;

(3) Prejudgment interest; and

(4) All cost incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5183(c) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) That Relator be awarded the maximum amount allowed as a Relator's Share under State law;

(4) An award of reasonable attorney's fees and costs; and

(5) Such further relief as this Court deems equitable and just.

COUNT 11
DELAWARE FALSE CLAIMS AND REPORTING ACT

377. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

378. This is a *qui tam* action brought by Realtor on behalf of the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

379. 6 Del. C. § 1201 (a) provides liability for any person who:

(1) knowingly presents, or causes to be presented directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; or
(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

380. In addition, 31 Del. C. § 1005 governs kickback schemes and states in part:

(a) It shall be unlawful for any person to solicit or receive any remuneration (including kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind:

(1) In return for referring an individual to a provider for the furnishing or arranging for the furnishing of any medical care or medical assistance for which payment may be made in whole or in part under any public assistance program; or

(2) In return for purchasing, leasing, ordering or arranging for or recommending purchasing, leasing, or ordering any property, facility, service or item of medical care or medical assistance for which payment may be made in whole or in part under any public assistance program.

31 Del. C. § 1005.

381. The off-label marketing and promotion, misbranding and the kickback schemes detailed above are nationwide. This conduct and these practices occur in every state in the country by Merit personnel, including in Delaware. Defendant violated 31 Del. C. § 1005 by engaging in the kickback scheme and related conduct described in this Complaint.

382. Defendant furthermore violated 6 Del. C. § 1201(a) by: (1) knowingly causing hundreds of thousands of false claims to be made, used and presented to the State of Delaware; (2) causing false records or statements to get a false or fraudulent claim paid or approved by the State; and (3) conspiring to defraud the State by getting a false or fraudulent claim allowed or paid. It is also liable by virtue of its systematic violation of Federal and state laws, including the FDCA, FCPA, Federal Anti-Kickback Act, and the Anti-Kickback Act, and 31 DeL C. § 1005 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

383. The State of Delaware, by and through the Delaware Medicaid program and other state healthcare programs, paid the claims submitted by healthcare providers and third party payers in connection therewith -- an outcome which was intended by the Defendant.

384. The State was unaware of this fraud, and could not have uncovered the Defendant's scheme absent this disclosure by the Relator.

385. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with Defendant's conduct. To be eligible to receive reimbursement as a provider, compliance with

applicable Delaware statutes, regulations and pharmacy manuals was mandatory. The claims submitted by Delaware providers in connection with Defendant's equipment, devices, and products violated federal and state laws as well as the Delaware provider agreements and should not have been paid.

386. Had the State of Delaware known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims caused to be submitted by Defendant through healthcare providers and third party payers in connection with that conduct.

387. As a result of Defendant's violation of 6 Del. C.§ 1201(a), the State of Delaware has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

388. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of himself and the State of Delaware.

389. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claims and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

WHEREFORE, Realtor respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Delaware:

(1) Three times the amount of actual damages which the state of Delaware has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendant caused to be presented to the State of Delaware;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 6 Del C. § 1205, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) That Relator be awarded the maximum amount allowed as a Relator's Share under State law;

(4) An award of reasonable attorneys' fees and costs; and

(5) Such further relief as this Court deems equitable and just.

COUNT 12
NEVADA FALSE CLAIMS ACT

390. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

391. This is a *qui tam* action brought by Relator on behalf of the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. Ann § 357.010, *et. seq.*

392. Nev. Rev. Stat. Ann. § 357.040 provides liability as follows:

1. Except as otherwise provided in NRS 357.050, a person who, with or without specific intent to defraud, does any of the following listed acts is liable to the State or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $5,000 or more than $10,000 for each act:

(a) Knowingly presents or causes to be presented a false claim for payment or approval.

(b) Knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim.

(c) Conspires to defraud by obtaining allowance or payment of a false claim.

...

(g) Knowingly makes or uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State or a political subdivision.

(h) Is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the State or political subdivision within a reasonable time.

393. In addition, Nev. Rev. Stat. Ann. § 422.560 prohibits the solicitation, acceptance or receipt of anything of value in connection with the provision of medical goods or services for which payment may be made in whole or in part under the Nevada Medicaid program.

394. The off-label marketing and promotion, misbranding and the kickback schemes detailed in this Complaint occur nationwide. This conduct and these practices occur in every state in the country by Merit personnel, including in Nevada. Defendant violated Nev. Rev. Stat. Ann. § 422.560 by engaging in the kickback scheme and related conduct described in this Complaint.

395. Defendant furthermore violated Nev. Rev. Stat. Ann. § 357:040(1) by: (1) knowingly causing hundreds of thousands of false claims to be made, used and presented to the State of Nevada; (2) causing false records or statements to get a false or fraudulent claim paid or approved by the State; (3) conspiring to defraud the State by getting a false or fraudulent claim allowed or paid; and (4) making or using or causing

to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State or a political subdivision. It is also liable by virtue of its systematic violation of Federal and state laws, including the FDCA, FCPA, Federal Anti-Kickback Act, and Nev. Rev. Stat. Ann. § 422.560, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

396. The State of Nevada, by and through the Nevada Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith, an outcome which was intended by the Defendant.

397. The State was unaware of this fraud, and could not have uncovered the Defendant's scheme absent this disclosure by the Relator.

398. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with Defendant's conduct. To be eligible to receive reimbursement as a provider, compliance with applicable Nevada statutes, regulations and pharmacy manuals was mandatory. The claims submitted by Nevada providers in connection with Defendant's equipment, devices and products violated federal and state laws as well as the Nevada provider agreements and should not have been paid.

399. Had the State of Nevada known that Defendant was violating the Federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or

were premised on false and/or misleading information, it would not have paid the claims caused to be submitted by Defendant through healthcare providers and third party payers in connection with that conduct.

400. As a result of Defendant's violations of Nev. Rev. Stat. Ann.§ 357.040(1), the State of Nevada has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

401. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Nev. Rev. Stat. Ann.§ 357.080(1) on behalf of himself and the State of Nevada.

402. This Court is requested to accept pendant jurisdiction of this related state claim and it is predicated upon the exact same facts as the Federal claims and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State Of Nevada:

(1) Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $2,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Nevada;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.R.S. § 357.210 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) That Relator be awarded the maximum amount allowed as a Relator's Share under State law;

(4) An award of reasonable attorneys' fees and costs; and

(5) Such further relief as this Court deems equitable and just.

COUNT 13
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

403. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

404. This is a *qui tam* action brought by Realtor on behalf of the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:437.1 *et seq.*

405. La. Rev. Stat. Ann. § 46:438.3 provides:

A. No person shall knowingly present or cause to be presented a false or fraudulent claim.

B. No person shall knowingly engage in misrepresentation or make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim.

C. No person shall knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the medical assistance programs, or to knowingly conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs.

D. No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

E. (1) No person shall knowingly submit a claim for goods, services, or supplies which were medically unnecessary or which were of substandard quality or quantity.

406. In addition, La. Rev. Stat. Ann. § 46:438.2 prohibits the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing healthcare, goods or services paid for in whole or in. part by the Louisiana Medical Assistance Programs.

407. The off-label marketing and promotion, misbranding and the kickback schemes detailed in this Complaint occur nationwide. This conduct and these practices occur in every state in the country by Merit's personnel, including in Louisiana. Defendant violated La. Rev. Stat. Ann. § 46:438.2(A) by engaging in the kickback scheme and related conduct described in this Complaint.

408. Defendant furthermore violated La. Rev. Stat. Ann. §46:438.3 by: (1) knowingly causing hundreds of thousands of false claims to be made, used and presented to the State of Louisiana; (2) causing false records or statements to get a false or fraudulent claim paid or approved by the State; and (3) conspiring to defraud the State by getting a false or fraudulent claim allowed or paid. It is also liable by virtue of its systematic violation of Federal and state laws, including the FDCA, FCPA, Federal Anti-Kickback Act, and La. Rev. Stat. Ann. §46:438.2(A), and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

409. The State of Louisiana, by and through the Louisiana Medicaid Program and other State healthcare programs, paid the claims submitted by healthcare providers and third party payers in connection therewith, an outcome which was intended by the Defendant.

410. The State was unaware of this fraud, and could not have uncovered the Defendant's scheme absent this disclosure by the Relator.

411. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Louisiana in connection with Defendant's conduct. To be eligible to receive reimbursement as a provider, compliance with applicable Louisiana statutes, regulations and pharmacy manuals was mandatory. The claims submitted by Louisiana providers in connection with Defendant's equipment, devices and products violated federal and state laws as well as the Louisiana provider agreements and should not have been paid.

412. Had the State of Louisiana known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims caused to be submitted by Defendant through healthcare providers and third party payers in connection with that conduct.

413. As a result of Defendant's violations of La. Rev. Stat. Ann. § 46:438.3 the State of Louisiana has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

414. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. Ann. § 46:437.1 *et. seq.* on behalf of himself and the State of Louisiana.

415. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claims, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State Of Louisiana:

(1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Louisiana;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to La. Rev. Stat. § 46:437.1 *et. seq.* and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) That Relator be awarded the maximum amount allowed as a Relator's Share under State law;

(4) An award of reasonable attorneys' fees and costs; and

(5) Such further relief as this Court deems equitable and just.

COUNT 14
HAWAII FALSE CLAIMS ACT

416. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

417. This is a *qui tam* action brought by Relator on behalf of the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. 661-21 *et seq.*

418. Haw. Rev. Stat. § 661-21(a) provides liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or-fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> ...
>
> (7) Is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim; or
>
> (8) Conspires to commit any of the conduct described in this subsection,

419. The false and misleading off-label marketing and promotion, misbranding and the kickback schemes detailed in this Complaint occur nationwide. This conduct and these practices occur in every state in the country by Merit personnel, including in Hawaii. Defendant violated Haw. Rev. Stat. §661-21(a) by: (1) knowingly causing hundreds of thousands of false claims to be made, used and presented to the State of Hawaii; (2) causing false records or statements to get a false or fraudulent claim paid or approved by the State; (3) conspiring to defraud the State by getting a false or fraudulent claim allowed or paid; and (4) failing to disclose the false claim to the State within a reasonable time after discovery of the false claim. It is also liable by virtue of its systematic violation of Federal and state laws, including the FDCA, FCPA, and the Federal Anti-Kickback Act, and by virtue of the fact that none of the claims

submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

420. The State of Hawaii, by and through the Hawaii Medicaid program and other State healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith, an outcome which was intended by the Defendant.

421. The State was unaware of this fraud, and could not have uncovered the Defendant's scheme absent this disclosure by the Relator.

422. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Hawaii in connection with Defendant's conduct. To be eligible to receive reimbursement as a provider, compliance with applicable Hawaii statutes, regulations and pharmacy manuals was mandatory. The claims submitted by Hawaii providers in connection with Defendant's equipment, devices and products violated federal and state laws as well as the Hawaii provider agreements and should not have been paid.

423. Had the State of Hawaii known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims caused to be submitted by Defendant through healthcare providers and third party payers in connection with that conduct.

424. As a result of Defendant's violations of Haw. Rev. Stat. § 661-21(a), the State of Hawaii has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

425. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of himself and the State of Hawaii.

426. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claims and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

WHEREFORE, Realtor respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the State of Hawaii:

(1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendant's illegal conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Hawaii;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Haw. Rev. Stat. §661-27 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) That Relator be awarded the maximum amount allowed as a Relator's Share under State law;

(4) An award of reasonable attorneys' fees and costs; and

(5) Such further relief as this Court deems equitable and just.

COUNT 15
DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

427. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.

428. This is a *qui tam* action brought by Relator and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-381.01 *et seq.*

429. D.C. Code § 2-381.02(a) provides liability for any person who:

> (1) Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;
>
> (3) Conspires to defraud the District by getting a false claim allowed or paid by the District;
>
> ...
>
> (7) Knowingly makes or uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District;
>
> (8) Is a beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District; or

430. In addition, D.C. Code § 4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

> (1) Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid Program; or
>
> (2) Recommending the purchase, lease, or order of any good, facility, service, or

item for which payment may be made under the District of Columbia Medicaid Program.

431. The false and misleading off-label marketing and promotion, misbranding and the kickback schemes detailed in this Complaint occur nationwide. This conduct and these practices occur in every state in the country by Merit employees and agents, including in the District of Columbia. Defendant violated D.C. Code § 4-802(c) by engaging in the illegal conduct, kickback scheme and other related conduct described in this Complaint.

432. Defendant furthermore violated D.C. Code § 2-308.14(a) by: (1) knowingly causing hundreds of thousands of false claims to be made, used and presented to the District; (2) causing false records or statements to get a false or fraudulent claim paid or approved by the State; (3) conspiring to defraud the State by getting a false or fraudulent claim allowed or paid; and (4) by failing to disclose the false claim to the District. It is also liable by virtue of its systematic violation of Federal and state laws, including the FDCA, FCPA, Federal Anti-Kickback Act, and, D.C. Code § 4-802(c), and by virtue of the fact that none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the government-funded healthcare programs.

433. The District of Columbia, by and through the District of Columbia Medicaid Program and other District healthcare programs, paid the claims submitted by healthcare providers and third party payers in connection therewith – an outcome intended by the Defendant.

434. The State was unaware of this fraud, and could not have uncovered the Defendant's scheme absent this disclosure by the Relator

435. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the District of Columbia in connection, with Defendant's illegal conduct. In order to be eligible to participate in and receive reimbursement as a provider, compliance with applicable D.C. statutes, regulations, pharmacy manuals as well as "with applicable federal and district standards for participation in Title XIX of the Social Security Act" was mandatory. (Department of Health Care Finance Medicaid Provider Agreement). The claims submitted by the District of Columbia providers in connection with Defendant's equipment, devices, and products violated federal and state laws as well as the District of Columbia provider agreements and should not have been paid.

436. Had the District of Columbia known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims caused to be submitted by Defendant through healthcare providers and third party payers in connection with that conduct.

437. As a result of Defendant's violations of D.C. Code § 2-308.14(a) the District of Columbia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

438. Realtor is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of himself and the District of Columbia.

439. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the District of Columbia:

(1) Three times the amount of actual damages which the District of Columbia has sustained as a result of Defendant's illegal conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the District of Columbia;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to D.C. Code § 2-308.15(f) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) That Relator be awarded the maximum amount allowed as a Relator's Share under State law;

(4) An award of reasonable attorneys' fees and costs; and

(5) Such further relief as this Court deems equitable and just.

COUNT 16
COMMONWEALTH OF VIRGINIA

440. All paragraphs of this Complaint are realleged and expressly adopted and incorporated as if fully set forth herein again.